Risk Analysis for Importation of Classical Swine Fever Virus in Swine and Swine Products from the European Union

December 2000

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United States Department of Agriculture
Animal and Plant Health Inspection Service
Veterinary Services

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Definitions

Breeding swine and swine semen model

a = number of swine semen shipments per year

b = the "risky period" or the period during which undetected CSF exists in areas outside of specially controlled areas, i.e., outside of established protection and surveillance zones, within the EU from time of initiation of disease to implementation of movement controls.

d = the number of breeding swine or swine semen shipments per year

e = the number of breeding herds or swine semen centers per shipment

de = the number of breeding herds or swine semen centers selected for export per year

f = the number of animals selected for export from a given breeding herd or swine semen center

g = the number of infected breeding herds or swine semen centers eligible for export with undetected CSF in the EU

h = the total number of breeding herds or swine semen centers eligible for export in the EU

g/h = the probability that a randomly selected breeding herd or swine semen center has undetected CSF

i = the probability that an animal selected from an infected breeding herd or swine semen center is CSF-infected

Swine semen model

k = the number of infected donor boars held for observation

m = probability that a CSF-infected boar will show clinical signs sufficient to allow diagnosis within a 40 day quarantine

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Pork Model

Q = the number of pigs slaughtered to provide pork for export to the US

P = the probability that a given pig is CSF-infected

N = the number of boxes of pork produced from a slaughtered pig

F2 = the fraction of imported pork used by restaurants

F3 = the probability that a box is trimmed by restaurants and the trimmings put in waste uncooked

F4 = the probability that waste from a restaurant or institution is collected by a waste feeder

F5 = the probability that a waste feeder does not cook waste adequately to kill CSF virus

F6 = the probability that CSF-contaminated waste fed to swine causes an outbreak

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Executive Summary

Classical swine fever (CSF), also known as hog cholera, is a highly contagious disease of swine that is exotic to the United States (US) [1, 2]. The disease was eradicated from the US in 1976 after a 16 year effort that cost the United States Department of Agriculture (USDA) and individual States approximately $140 million (1976 dollars) [2]. In 1997 dollars, this program would cost about $525 million.

Until 1997, the USDA, Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) prevented the reintroduction of CSF into the US by prohibiting the importation of live swine, unprocessed pork, or swine products from any country affected with CSF [3, 4], except under special conditions designed to mitigate risk. An example of such conditions is the on-site APHIS oversight (including testing for disease) of swine semen donor export operations from France during a period when APHIS considered France to be affected with CSF [5]. The only products allowed from CSF-affected countries were those processed in a manner known to inactivate CSF virus [3]. Import prohibition applied to an entire country, even though CSF outbreaks might be limited to a defined region within the country.

Recently, however, APHIS changed its import policy to incorporate the concepts of regionalization based on risk assessment [6, 7]. The new approach to the importation of animals and animal products recognizes that borders other than national boundaries can define regions and that discrete regions in a country may present different levels of animal disease risk. This approach is consistent with APHIS obligations under the North American Free Trade Agreement and the World Trade Organization Sanitary and Phytosanitary agreements. It provides the basis for the present analysis of the risk of introducing CSF into the US with breeding swine, swine semen, and fresh pork imported from a region within the European Union (EU) in which CSF is not known to exist.

Before adopting a regionalization policy, the US considered disease status in Europe on a country-by-country (Member State) basis. However, after the Member States merged into a single EU in 1994 and the US implemented its regionalization policy in 1997, the US considered the EU as a single entity. Without regional recognition, the US would consider the entire EU to be affected by CSF. Importation of swine or unprocessed swine products from the EU would be prohibited.

This risk assessment was conducted in response to a request from the European Commission (EC) that the US recognize certain regions within the EU as CSF-free. The EU requested recognition of the regions it considered to be CSF-free so that it could export breeding

swine, swine semen, and pork and pork products from these areas to the US. APHIS evaluated risk based on epidemiological data from the EU and the effectiveness of the internal EU control mechanisms.

Quantitative Assessment (Initial Analysis, Section I)

APHIS conducted a quantitative risk assessment to estimate the probability that CSF would be imported with breeding swine, swine semen and fresh or frozen pork from the EU. The analysis of live animals was limited to breeding swine since the importation of other live swine would not be cost-effective.

The risk assessment considered epidemiological characteristics of CSF in the EU that were described in a series of documents provided to USDA by the EU [8]. These documents provided information used to develop a quantitative model and estimate the input variables defined subsequently for the quantitative assessment.

Epidemiological data showed that the disease spread through movement of domestic animals (primarily pigs for fattening or slaughter); transmission from wild boars; movement of people, vehicles or equipment contaminated with virus; or distribution of contaminated semen [2, 9-12]. The initial quantitative report does not attempt to differentiate among these pathways. It analyzes risk based on disease transmission data resulting from the collective pathways. However, spatial and temporal relationships of individual pathways are addressed in a descriptive supplemental assessment prepared in a Geographic Information Systems (GIS) format and included in this report as Section II.

The EU provided documentation on veterinary infrastructure and regulations, movement controls, disease status and epidemiology in the regions and adjacent regions, disease control programs, control of animal and product movement, livestock demographics and marketing practices, and disease surveillance in the context of disease epidemiology in the EU. Relevant EU regulations for live animals require internal veterinary certifications for transport of animals and define procedures for management of outbreaks (including a stamping-out policy), plans to address spread from wild boars, and quarantine and testing requirements for breeding swine and swine semen donors [13, 14]. These regulations are designed to control CSF transmission within and between Member States. These are harmonized and binding on all Member States.

The data provided by the EU were generated under the conditions defined in these regulations. Therefore, on the one hand, the risk assessed does not reflect a completely unmitigated baseline because these regulations have a mitigating effect. On the other hand, some of data used in this assessment were generated during a severe CSF outbreak that

occurred in The Netherlands in 1997 and 1998. Implementation of the EU regulations was not completely effective during this outbreak [12, 15]. In fact, this outbreak is considered the most severe the EU has ever experienced [16]. EC officials have analyzed the situation, identified problem areas, discussed ways to address those problems, [17], and are developing new legislation to correct the problems identified [18]. In any event, the quantitative levels of risk assessed in this report reflect both the mitigating effects of the EU regulations and the severe outbreak in The Netherlands.

A summary table of results of the quantitative analysis is presented on the next page. The results are expressed as the most likely value for the probability of one or more incursions of infected swine, semen shipments, or boxes of pork into the US in a given year. They are also expressed as the most likely frequency of incursions (i.e., the expected mean time between incursions or the expectation that there would be one or more incursions into the US of infected swine, fresh pork, or semen shipments within the number of years reported). Ranges describing variability of the probability and frequency values summarized here are reported subsequently in the body of the report and in Section I: Sensitivity Analysis.

The quantitative risk estimate for introducing CSF into the US by breeding swine was one or more incursions in an average of 33,670 years. Since the risk identified was extremely low, no additional mitigations are reported.

The risk estimate for introducing CSF by swine semen was one or more incursions in an average of 1,842 years. This risk appeared significantly greater than that assessed for breeding swine or fresh pork, and so an additional mitigation was considered. Specifically, APHIS assessed the mitigating effects of holding semen donor boars and observing them clinically for 40 days after semen collection. This 40-day holding period is in addition to the 30-day holding period required by EU legislation [19] before the animals may enter an approved EU semen center. Adding this mitigation reduced this risk estimate to one or more incursions in an average of 8,090 years.

The risk estimate for introducing CSF in fresh or frozen pork was one or more incursions in an average of 22,676 years. Since the risk level was very low, no additional mitigations are reported.

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The following table provides a summary of the quantitative data:

Risk Estimate Summary for Importation of Breeding Swine, Swine Semen and Fresh or Frozen Pork into the United States from the EU

	Values from Initial Assessment		*Mitigated Values*	
Model	Probability[3]	Frequency[4]	Probability[3]	Frequency[4]
Breeding swine[1]	2.97×10^{-5}	33,670	Not reported	Not reported
Swine semen[2]	5.43×10^{-4}	1,842	1.24×10^{-4}	8,090
Pork[1]	4.41×10^{-5}	22,676	Not reported	Not reported

[1]Mitigating effects are not reported for breeding swine or pork since the probability calculated from the initial assessment is extremely low.

[2]Mitigating effect of holding semen donor boars for 40 days after collection of semen and observing the animals for clinical signs is assessed.

[3]Probability is assessed as the likelihood of one or more incursions per year (most likely value). Variability and uncertainty in the output, including estimated maximum and minimum values, is described subsequently in the report. Results are reported to four significant figures. These reflect the actual values calculated. Expression to four significant figures is not intended to imply a high level of precision.

[4]Frequency is assessed as the expected mean time between incursions or the expectation that there would be one or more incursions within the number of years reported (most likely value). Variability and uncertainty in the output, including estimated maximum and minimum values, is presented subsequently in the report. Results are reported to four significant figures. These reflect the actual values calculated. Expression to four significant figures is not intended to imply a high level of precision.

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Spatial and Temporal Considerations: Geographic Information Systems (GIS) Analysis (Supplemental Analysis, Section II)

The purpose of this supplemental assessment is to describe, with the aid of geographic data, the spatial and temporal patterns of CSF outbreaks that have occurred in the EU since 1997. This analysis was conducted because certain EU Member States had reported outbreaks in domestic swine that had originated from wild boar. APHIS has considered the risk from regions in which CSF was detected in domestic swine to be unacceptably high and has prohibited importation of material from these regions by removing them from its list of CSF-free areas as soon as disease was identified in domestic pigs [3, 4].

However, concerns were raised about the continuing potential for disease transmission from these regions into unaffected regions and about the potential for this transmission to affect the results of the quantitative assessment. To address these concerns, outbreak and demographic data from these regions are included here and compared with overall disease transmission pathways in the EU in order to assess whether disease originating from these CSF-affected regions might affect the risk estimates generated in the quantitative assessment.

The information is presented in a GIS format to provide insight on different areas of the EU regarding frequency of CSF outbreaks in domestic swine herds, patterns of disease transmission, efficacy of EU control mechanisms, and the magnitude of EU outbreaks. In its assessment of risk, APHIS considers the following relationships:

1. To address the relative risk of disease originating from wild boar, APHIS assesses relationship between disease in domestic swine to location of areas with uninfected wild boar, infected wild boar, and no wild boar:

2. To address the relative risk of disease transmission by animal movement, APHIS assesses movement patterns of domestic swine in relationship to disease transmission patterns in the 1997-1998 outbreak:

3. To address the relative risk of disease transmission by lateral spread in domestic swine, APHIS assesses domestic swine density in relationship to disease transmission patterns in The Netherlands;

4. To address the relative risk of disease transmission from wild boar to domestic swine, APHIS assesses domestic swine density in relationship to proximity to wild boar populations (e.g., close proximity and geographically distant from wild boar); and

5. To address the effects of EU control mechanisms over time, which should reflect the effect of increased monitoring since the 1997-1998 outbreak, APHIS assesses the extent of disease spread (e.g., primary, secondary, tertiary) over time and between areas with and without infected wild boar.

The patterns described suggest that, since 1997, the extent and spread of disease originating from wild boar has not been as great as that associated with the outbreak in domestic swine in 1997. This is based on comparisons of epidemiological observations of recent disease outbreaks originating in wild boar with spread in domestic swine during the 1997-1998 epidemic. Although the EU epidemic may have originated in wild boar, no subsequent outbreaks originating from wild boar have spread to the extent seen in that outbreak. Furthermore, the extent of secondary and tertiary spread from outbreaks originating in wild boar has decreased with time.

APHIS attributes the reduction in the spread of disease from wild boar over time to surveillance and control activities required by the EU in areas with infected wild boar. Movement of domestic pigs from these areas is restricted by EU legislation. APHIS intends to ensure the effectiveness of these control measures by prohibiting imports from areas under EU restrictions because of CSF.

APHIS considers the possibility that export from areas in close proximity to infected wild boar might constitute a risk. However, the descriptive observations suggest that the risk of importing CSF-infected material from areas of the EU that are in close proximity to infected wild boar is not greater than the risk of importing infected material from areas that are geographically distant from outbreaks in wild boar. These observations, taken together with increased attention to surveillance and control activities for CSF in wild boar that the EU documented to APHIS [17-18] led APHIS to conclude that disease transmission patterns from wild boar to domestic swine should not affect the quantitative risk estimated in Section I of this report.

APHIS considered the possibility that CSF outbreaks might occur more frequently in areas with high-density swine populations than in areas with low-density swine populations. The descriptive observations did not support that possibility.

APHIS also considered the possibility that the extent of secondary spread is greater after CSF is introduced into areas with high-density swine populations than when it is introduced into areas with low-density swine populations. Observations from the 1997-1998 outbreak did support that hypothesis.

Taken together, these observations of domestic swine demographics suggest that high densities of swine are not a good predictor of regions that may experience CSF outbreaks. However, once CSF is introduced, spread is more extensive in regions with high densities of domestic swine.

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Section I: Quantitative Assessment

Introduction

CSF, also known as hog cholera, is a highly contagious disease of swine that is exotic to the US [1, 2]. The disease was eradicated from the US in 1976 after a 16 year effort which cost the United States Department of Agriculture (USDA) and individual States approximately $140 million [2]. Today this program would cost about $525 million (1997 dollars). The potential for reintroduction of CSF into the US is a major concern, not only because of the cost of eradication, but also because introduction of the disease would have a significant adverse effect on international trade.

USDA, APHIS, VS, historically approached exotic or foreign animal disease exclusion, including that of CSF, with a "zero risk" policy, except under special conditions negotiated specifically to mitigate disease [5]. Specifically, VS prohibited the importation of swine, swine semen, or unprocessed swine products from any country affected with exotic swine diseases, including CSF [3, 4]. Importation of fresh or frozen pork was prohibited [4]. Pork products could be imported only if they were processed in a manner known to inactivate the CSF virus. These prohibitions applied to the entire country, even if CSF affected only a limited region within that country.

Recently, however, APHIS changed its import requirements to incorporate the concepts of regionalization based on risk assessment. The new approach to the importation of animals and animal products was described in a policy statement [6] and regulatory changes [7] published originally in 1997. The legislation and policy recognize that regions presenting different levels of animal disease risk may be defined by borders other than national boundaries. This approach is consistent with APHIS obligations under the North American Free Trade Agreement and the World Trade Organization Sanitary and Phytosanitary Agreement (SPS), and provides the basis for assessing the risk of introducing CSF into the US as a contaminant of breeding swine, swine semen, and fresh pork imported from the EU.

Description of Request and Action Taken

APHIS received a request from the European Commission (EC) that the US recognize defined regions within the EU as CSF-free [20]. Some of these regions constituted limited areas within certain Member States. The EC provided information demarcating affected from unaffected regions, documented the process by which these regions were defined, and described control measures for disease in affected regions. The EC implements various restrictions, including prohibition of movement out of the area, that are designed to control spread of disease in areas in which disease outbreaks occurred [13].

Relevant to this, the APHIS regionalization policy roughly equates the prior concept of disease freedom to a new concept of acceptable risk or risk mitigated to acceptable levels. US recognition of areas with acceptable risk or mitigations resulting in acceptable risk would enable those areas to export swine and swine products to the US. The EC and individual Member States submitted extensive documentation in support of this request [8]. A map of the EU Member States is provided as Figure 1 for reference.

APHIS conducted two assessments. The results of both assessments are reported here. The first assessment (Section I) used quantitative models to evaluate the risk of importing CSF-infected animals, semen, or fresh/frozen pork into the US during undetected outbreaks in the EU. Sensitivity analyses were conducted on input values for the model (Section I: Sensitivity Analysis). The initial analysis was limited to regions that the EU defined as CSF-free.

APHIS personnel evaluated the information provided by the EC on outbreak history and epidemiology in the context of CSF epidemiology in the EU [2, 10]. APHIS defined an undetected outbreak as a situation in which CSF was undetected prior to export of the animal or product from a breeding swine herd, a swine semen center, or a fattening/finishing operation. APHIS evaluated risk to the US as the probability that an undetected CSF-infected animal, semen sample, or box of pork would reach the US. It also evaluated the potential that waste from a box of infected fresh pork entering the US would be fed to swine.

APHIS assumed that an outbreak would result from an incursion, i.e., importation into the US of a single infected animal, swine semen shipment, or box of infected pork discarded by restaurants and institutions and fed to swine. This report describes the quantitative assessment of these risks conducted by APHIS under the control mechanisms currently required under EC regulations. APHIS intends to ensure that the effects of these mechanisms will be maintained by prohibiting imports from regions under EU restrictions because of CSF. However, the input variables also reflect data derived from an extremely severe outbreak that occurred in The Netherlands in 1997 and 1998 and spread through several other EU Member States [9, 12, 15-16].

The second assessment (Section II) was a descriptive assessment that evaluated spatial and temporal aspects of CSF transmission from affected to unaffected regions within the EU. Data provided by the EU were entered into a comprehensive database and are reported in a GIS format. The results of this analysis are provided in Section 2 of this report.

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OIE Code Requirements for Risk Analysis

The format of this assessment conforms with the guidance on risk analysis provided by the OIE Code [21]. General aspects of the guidelines are summarized here for reference.

Hazard Identification

OIE guidelines state that a risk analysis must start with hazard identification [21]. The definition of hazard should identify the pathogenic agent of concern, the species being considered for importation, and the commodity.

APHIS defined the hazard as importation of undetected CSF virus in breeding swine, swine semen, or fresh/frozen pork into the US. APHIS considered the probability that swine in the US would ingest CSF-infected waste as part of this hazard.

Risk Analysis

The OIE Code describes four basic components of a risk analysis [21]. These are a release assessment, an exposure assessment, a consequence assessment, and a risk estimation. Each of these components is discussed individually for the quantitative assessment.

<u>Release Assessment</u>

The OIE recommends that a release assessment address the impact of biological factors, country factors, and commodity factors on the biological pathways through which CSF could be imported. The quantitative assessment conducted by APHIS provides an estimate of the probability that CSF could enter the US in an undetected infected animal, swine semen sample, or a box of fresh/frozen pork and result in an outbreak. Risk is expressed quantitatively as both the probability of at least one disease incursion (or outbreak) and the expected frequency of incursions (i.e., mean time between incursions or the expectation that there would be at least one incursion in the number of years reported). The latter unit, expected frequency, is a value that has been used routinely by APHIS decision-makers.

Although presented as a separate section of this report, APHIS considers the GIS evaluation as part of the release assessment. It evaluates spatial and temporal aspects of disease transmission from affected to unaffected regions within the EU, and its primary focus is country factors that would affect the potential for outbreaks within the EU.

Exposure Assessment

The OIE recommends that an exposure assessment describe the biological pathways necessary for exposure of US swine to CSF [21]. OIE suggests that the exposure assessment, like the release assessment, consider biological factors, country factors, and commodity factors affecting the pathway. It should estimate the probability that CSF can spread to US livestock after import.

APHIS conservatively addresses exposure by assuming that the CSF virus is extremely infectious, so much so that a single incursion of virus entering the US in a live animal or semen sample will result in an outbreak. Therefore, in the quantitative breeding swine and swine semen models, the results of the release assessment and exposure assessment are the same. In the quantitative pork model, the probability of entry and the probability that US livestock will ingest contaminated pork scraps are assessed. The final results of all of the quantitative models reflect a combined release/exposure assessment.

Consequence Assessment

The OIE Code recommends that consequence assessment describe the relationship between exposure to the hazard and consequences of those exposures [21]. It is intended to define the consequences of exposure and estimate an associated probability. The Code also states that, if the release assessment or exposure assessment demonstrates no significant risk, the risk assessment may conclude. Because the risks estimated for release and exposure (either existing under current conditions or mitigated by a quarantine period for semen donor boars) were very small, a consequence assessment was not considered necessary. Therefore, APHIS did not conduct a formal consequence assessment for the quantitative models.

Risk Estimation

Finally, the Code defines risk estimation as the process of integrating the results from the release assessment, exposure assessment, and consequence assessment to produce an overall assessment of risks associated with the hazard identified at the outset. Since a consequence assessment was not conducted, APHIS also did not conduct a separate risk estimation.

Release/exposure Assessment for the Quantitative Models

Biological Factors

CSF is spread by several pathways: (a) exposure to infected wild boars, either through contact or by garbage feeding; (b) movement of infected domestic swine; (c) movement of

people and equipment contaminated with CSF virus; (d) contaminated semen [2, 9-10]. Disease followed each of these pathways in the 1997-1998 outbreak. A priority ranking of these factors, based on experience obtained between 1993 and 1995, showed that more than half of the outbreaks in Germany resulted from contact with wild boar and more than a quarter of secondary outbreaks resulted from trade in pigs. Contaminated semen from a semen collection center was a factor in the 1997-1998 epidemic in The Netherlands [9].

A list of the outbreaks occurring in Member States reporting outbreaks in domestic swine between 1993 and 2000 is presented in the following Table 1 [15].

Table 1. CSF Outbreaks in Domestic Pigs EU Member States between 1993 and 2000

1993	1994	1995	1996	1997	1998	1999	2000
Germany	Germany	Germany	Germany	Germany	Germany	Germany	Germany
Italy	Italy	Italy	Italy	Italy	Italy	Italy	Italy
Belgium	Belgium			Belgium			
France							
	Austria	Austria	Austria				
				Netherlands	Netherlands		
				Spain	Spain		
							UK[1]

Transmission pathways within the EU are not distinguished for the quantitative assessment. For example, outbreak history in The Netherlands reflects transmission by transported pigs, infected semen donors in semen centers, and contaminated semen [9, 15]. The ultimate source for all of these pathways was probably infected wild swine. The issue of transmission through different pathways in the EU is addressed in the GIS assessment (Section II).

The end result of all disease transmission pathways combined is reflected in the input value for the quantitative assessments called the "risky period." This is defined as the period

[1] In August, 2000, a CSF outbreak occurred in three United Kingdom (UK) counties in East Anglia. APHIS is assessing risk from this outbreak separately. In this regard, data from the UK demonstrated that the virus type identified in East Anglia originated from Asia rather than the EU [22-23], suggesting that the infected source material was probably smuggled. APHIS considered this sufficient justification to exclude the UK outbreak from consideration since this analysis is limited to legal imports of undetected CSF-infected materials. However, the APHIS decision to handle this separately was also based on the long history of disease freedom and observations of an APHIS site visit team. This team evaluated the situation and concluded that the outbreak was being controlled adequately within the boundaries of East Anglia. APHIS published an interim rule prohibiting imports from East Anglia [24].

during which undetected CSF exists in areas within the EU outside of specially controlled areas (e.g., protection and surveillance zones) prior to detection of disease and implementation of movement controls.

Country Factors: Regions Considered in the Assessments

The original request from the EU was recognition of defined EU regions as CSF-free. Although the risk assessment was assessed based on data from the entire EU, APHIS excluded certain EU regions from its export considerations [25]. Risk from some of these regions had been evaluated previously as acceptable, and APHIS did not re-evaluate those regions. In this regard, the low risk regions that APHIS excluded were regions previously recognized as CSF-free and identified as such in the Code of Federal Regulations [3]. The low risk regions were the United Kingdom (UK) including Northern Ireland, the Republic of Ireland, Sweden, Finland, and Denmark. These are identified in Figure 2.

Although initially considered a low-risk region, because of an outbreak in domestic pigs that occurred in August 2000, East Anglia is now excluded from exporting swine, semen, and fresh pork to the US. APHIS is assessing risk from this outbreak separately. In this regard, data from the UK demonstrated that the virus type identified in East Anglia apparently originated from Asia rather than the EU [22, 23], suggesting that the infected source material was probably smuggled. APHIS considered this sufficient justification not to include data from the UK outbreak in its assessment since the analysis in this report is limited to legal imports of undetected CSF-infected materials. However, the APHIS decision to handle this separately was based also on the long history of disease freedom in the UK and observations of an APHIS site visit team [23], which evaluated the situation and concluded that the outbreak was being controlled adequately within the boundaries of East Anglia and in accordance with EU legislation [13]. APHIS published an interim rule prohibiting imports from East Anglia [24].

APHIS excluded two categories of high-risk regions from consideration for export, although the data collected for the analysis did not exclude information from these regions [25]. Examples of regions which were identified as unacceptable for export (at the time) during the course of the initial assessment are illustrated in Figure 2, Figure 2A and Figure 2B.

The first category of regions from which APHIS did not intend to accept exports at any time (either the time of the analysis or in the future) was regions with a history of outbreaks in domestic swine within the past 6 months. These regions were defined on the basis of OIE criteria that classify regions as free (in a country that does not practice vaccination and that exercises a stamping out policy) 6 months after the last case [26]. Two criteria of this definition are met because the EU does not practice vaccination, and it has a stamping-out

policy. To meet the third criterion, APHIS excluded regions from consideration for export in which one or more outbreaks had occurred in domestic swine within the 6-month period from June to December 1998. This was the data collection period for the May 3/June 2, 1999 assessment [25]. Since this document (November 30, 2000) is a revision of the May 3/June 2 assessment, it maintains the database. However, APHIS will continue to exclude regions meeting these criteria from consideration for export to the US, as such regions are identified. APHIS took this approach in its response to the recent UK outbreak.

The second category of regions from which exports would be excluded was based on the presence of infected wild boar within a region in which transmission from infected wild boar to domestic pigs was observed [9]. Presence of infected wild boar in a region might constitute a major risk factor. However, regions were identified in which outbreaks in domestic pigs did not always occur in regions containing infected wild boar. For example, CSF is known to be endemic in wild swine in northern Germany and Italy, possibly in some alpine areas in France [27-36], and was confirmed in a single wild boar in Austria on November 7, 2000 [37, 69]. However, despite the reservoir of infection in wild swine in France, there is no history of recent outbreaks where disease appeared to be transmitted from wild to domestic swine. Furthermore, there was no indication at the time of this report that CSF had spread to domestic swine in Germany or Austria. Areas like these could be considered CSF-free for export.

High-risk regions excluded from the initial quantitative assessment for consideration for export, identified in Figure 2 for illustration, were the following:

1) Germany: The Kreis Vechta in the landers of Lower Saxony, the Kreis Warendorf in the landers of North-Rhine Westfalen, and the Kreis Altmarkkreis Salzwedel in the landers of Saxony-Anhalt.[2] (Note: A lander is a Federal State and a Kreis is roughly equivalent to a U.S. county.) The location of these is illustrated in Figure 2 and Figure 2A.

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[2] Vechta, Warendorf, and Altmarkkreis Salzwedel were excluded from consideration for export on the basis of outbreaks in domestic swine that were confirmed on October 12, October 11, and November 20, 1998, respectively [40]. The outbreaks occurred within the 6-month period from June to December 1998 during which data were collected for the May 3/June 2 quantitative assessment [25]. Since this document is a revision of the May 3/June 2 assessment, it maintains the original database. However, no additional outbreaks were reported in these kreis in domestic swine between October 1998 and the time of preparation of this revision. Therefore, in accordance with OIE criteria [26] that define a region as free when it has been shown that CSF has not been present for at least the past 6 months, these regions may now be considered free. Although CSF was detected in Altenmarkkreis Salzwedel in wild boar in January, February, and March of 2000 [29], no transmission to domestic swine has been observed.

2) Italy: The Island of Sardinia and the regions of Piemonte and Emilia-Romagna.[3] The location of these regions is illustrated in Figure 2 and Figure 2B.

These high-risk regions were initially defined by APHIS the boundaries of the smallest veterinary administrative unit within the Member State, the local veterinary unit (LVU), rather than more restrictive control zones defined by the EU.

When the original version of the assessment [25] was released for comment, some commenters questioned the APHIS decision to exclude these areas from the assessment. In fact, data from the areas were not excluded from the quantitative input values. However, the areas met criteria that made them unacceptable sources for exported materials at the time.

In any event, the commenters expressed concern regarding the potential for spread from high-risk regions into regions that might be declared as CSF-free. In response to these comments, APHIS described spatial and temporal aspects of disease transmission from high-risk regions in the GIS assessment reported in Section II of this document.

Country Factors: CSF in Domestic Pigs

Large numbers of swine move freely between EU Member States and within Member States. [38-39]. Swine born in one Member State are routinely fattened or slaughtered in another. For example, in 1995, approximately 3.8 million pigs moved from one Member State to another for fattening, and 3.9 million pigs moved from one Member State to another for slaughter.

As summarized in Table 1 (page 12), at least one outbreak of disease in domestic pigs has occurred every year between 1993 and 2000 in one or more Member States [15, 40]. However, because this quantitative assessment is a revision of a pre-existing document [25], input values for the model were derived from the data collected between 1993 and 1998 for consistency with the earlier document.

Some of the outbreaks reported were attributed to transmission from infected wild boars. Others were attributed to movement of infected domestic pigs and/or movement of people and equipment. The source of some outbreaks was not identified. However, that was not critical for the quantitative assessment, which was based solely on epidemiological data describing confirmed outbreaks, irrespective of their source.

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[3] Piemonte and Emilia-Romagna were excluded from consideration for export on the basis of outbreaks in domestic swine that were confirmed in March 1999 [68], even though the outbreaks occurred after the June to December 1998 period. CSF has not been detected in domestic swine in these regions since that time, so they may be considered CSF-free by OIE criteria [26].

Once CSF is detected in the EU, control mechanisms must comply with EU legislation. This legislation specifies a stamping out policy, as well as a requirement that protection and surveillance zones be established around an outbreak [13]. Establishment of protection and surveillance zones (zones that will be defined more completely in the following section on EU control mechanisms) is consistent with OIE requirements. Disease control measures are initiated within the zone and movement of domestic animals out of the zone is prohibited. Rapid identification of disease and implementation of movement restrictions constitute critical components of the EU system for internal control of disease spread.

An outbreak of particular concern occurred in The Netherlands in 1997 [12]. Although this outbreak may have originated in wild boar in another country, it involved other pathways as well. However, transmission in The Netherlands occurred primarily by transport of infected swine over long distances. Pathways of disease spread in this outbreak are described in some detail in Section II: Spatial and Temporal Analysis.

The situation in The Netherlands appeared to be unique within the EU. It resulted in one of the biggest and most costly outbreaks ever occurring in the EU [16]. The two major reasons suggested for the severity of the outbreak were the relatively long period of time before the outbreak was detected and the density of swine and herds in the region [15]. Disease eradication in The Netherlands was complicated by several factors, including the late detection of the first infection; artificial insemination as an unexpected source of infection; the organization of pig farming in The Netherlands (characterized by highly concentrated production and dependence on the transport of stock from one unit to another), insufficient rendering capacity; and marketing practices that lead to a high proportion of adult pigs in the area that were less likely to show clinical signs than young animals [12].

Movement of infected fattening pigs spread disease to other countries in 1997. The epidemiological evidence surrounding this outbreak and its subsequent spread suggested that the stamping out policy was not effective. Apparently, actions to deter spread of disease (ban on insemination, preventive slaughter) did not address the problem quickly enough, even though the legislation was in place and binding on all Member States [9, 15].

The factors influencing disease spread have been analyzed carefully and the EU is taking action to ensure that future such problems are addressed adequately [17-18]. However, the situation in The Netherlands provided real data on spread from an extremely severe outbreak. These data were incorporated into the estimates for several input parameters. Moreover, to assess the stability of risk estimates, APHIS conducted analyses using varied input parameters. Results of these sensitivity analyses are reported in Section I: Sensitivity Analysis.

Risky Period

Because disease control mechanisms are enhanced within EU protection and surveillance zones, disease is more likely to spread from outbreak locations outside these zones. To address this, APHIS generated estimates for a "risky period" associated with outbreaks occurring **outside** of specially controlled areas, i.e., outside of established protection and surveillance zones.

As previously mentioned, APHIS assumed that infection was not present prior to time of infection (estimated from time of detection) in the region. Therefore, APHIS defined the "risky period" as the time from initiation of infection to the time a stamping-out policy was enforced, movement restrictions were implemented, and export ceased in areas on which the EU placed restrictions. APHIS defined these areas as zones that had been established by the EU and Member States [8] in close consultation with EU and Member State officials.

Data defining the risky period for individual Member States were derived from information provided for 1997, when it was estimated that 103 of 611 outbreaks occurred **outside** of any established protection and surveillance zones in the EU [8]. It follows that 508 of the outbreaks occurred within the previously established control zones. Infection from the 508 would not be expected to spread further because of the special restrictions, so estimates of the risky period were based on the 103 outbreaks. Member States in which infected herds were detected outside of surveillance and protection zones in this outbreak are identified in Figure 3.

Analysis of data submitted by the EU and consultation with EU officials revealed that the length of the risky period varied with each EU Member State. Epidemiological evidence suggested the disease was present in various regions from 7 days to nearly 8 weeks before it was detected and the stamping out process was initiated. These estimates were incorporated into the APHIS assessment of risk and addressed differential risks associated with various areas. Calculation of the actual input values will be discussed subsequently in the context of the model.

The type of swine operation was also taken into account in the assessment of risk. Specifically, APHIS evaluated individually the risks associated with breeding swine herds, swine semen collection centers, and fattening/finishing operations. For example, of the 103 outbreaks occurring outside of specially controlled areas, only one was a breeding swine operation and one was a swine semen center that engaged in export sales [11, 15]. The remaining operations were fattening farms, mixed operations, or feeder pig operations.

Outbreak data for each type of operation are reflected in the input values for the models evaluating risk from breeding swine, swine semen, and pork.

EU Control of CSF Spread

Animal health regulations within the EU are harmonized for all Member States. The EU system of internal controls is described in various EU Council Directives [14]. These include regulations relevant to the movement of animals and animal products, such as veterinary checks by the LVUs at the points of origin and points of destination. The current system replaced border veterinary checks that were abolished when the Internal Market was formed in 1994. These regulations include compulsory notification of OIE list A diseases, including CSF, and the requirement that laboratory tests for CSF must be performed on all sick swine if CSF suspected.

These regulations also include special emphasis on the potential for spread from wild boar to domestic swine [27, 34]. Contingency plans are implemented in areas with affected wild boar. These include movement restrictions for domestic animals. Laboratory tests for CSF are required for wild boar that are shot or found dead.

Protection and surveillance zones with characteristics defined in EU legislation are established around an outbreak in domestic swine [13]. Animals in the protection zone are depopulated. The surveillance zone is defined to surround the protection zone and, as the name suggests, surveillance in this zone is increased. The minimum requirements defined in the EU directives for stamping out an outbreak include definition of a protection zone with a radius of 3 kilometers from the outbreak location and a surveillance zone surrounding the protection zone of at least 10 additional kilometers.

Movement from the zones is restricted. Specifically, premises within the protection zone are prohibited from moving swine outside the zone for at least 30 days. Premises within the surveillance zone are prohibited from moving swine outside the zone for 15 days.

If outbreaks spread to new areas (as was observed in spread of the disease from The Netherlands to Spain in 1997), new protection and surveillance zones are established. Movement controls are established, and inspection and depopulation of the protection zone are initiated. In addition to these control measures, the EU has an extensive trace-back policy.

Animal and product movement is tracked in a computerized system called ANIMO [17, 41-43]. Data entry is mandated by EU law, although LVU personnel control the input. LVU personnel are also responsible for quality control at the local level, although some quality

control measures are administered by the contractor, the EU, and the EU Court of Auditors [9, 17]. The system is administered by a private contractor. Although the system is not designed specifically to track disease spread, it provides trace-back potential for domestic swine and swine product movement.

The EU also has regulations intended to control of spread through swine semen [19]. Of particular relevance to this assessment is the EU requirement that donors of swine semen moving in intra-community must be held in isolation for at least 30 days prior to entering a federally inspected semen collection center. The collection center must be approved for export by the veterinary services of the EU Member State in which it is located. Animals must be tested during the 30-day isolation period with a test for CSF approved by the OIE [26], and test results must be negative.

EC regulations for transport of swine semen among Member States specify more stringent certification requirements for semen donors than for other types of swine. These regulations require animals to be accompanied by a veterinary certificate of origin and prohibit their commingling with swine from CSF-affected areas.

Breeding Swine Model

The evaluation of live swine focused on breeding swine (i.e., seed stock swine). APHIS considered it unlikely that other live swine from the EU (e.g., feeder pigs) would be imported into the US because transportation costs would be prohibitive.

Import Assumptions for the Initial Assessment

APHIS relies on the OIE definition of a CSF-free country or zone as an area that practices a stamping out policy without vaccination. Therefore, APHIS assumes that an area with these characteristics can be designated as CSF free if a case of CSF has not been detected for at least 6 months [26].

APHIS assumes that the EU restrictions on movement of animals and animal products from CSF-affected areas have a mitigating effect on the risk of CSF transmission among and between Member States [14].

APHIS assumes that there are possible consequences from undetected CSF during a risky period in that portion of the EU being regionalized.

APHIS assumes that each shipment of breeding swine originates from a single breeding herd.

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Breeding Swine: Scenario Tree and Mathematical Model

Figure 4 presents a scenario tree describing the pathway proposed for introduction of CSF into the US from the EU via live breeding swine. Branch points are shown to facilitate conceptualization of the mathematical model. However, probabilities are not calculated for each branch point because the scenario tree does not describe a model that can address clustering effects. Infected animals are likely to occur in clusters. The probability of importing one or more infected animals cannot be calculated simply by multiplying the probabilities at each branch point in the tree because this approach would not incorporate the dependent nature of each branch point and the conditional nature of the probabilities. A simple multiplicative approach to this calculation of probability would require an assumption that the events described at each branch point are independent of one another, which is not the case.

Rather, for the breeding swine model, a binomial probability distribution [44-46] is used to estimate the risk associated with the importation of undetected CSF in live swine from the EU. A binomial is one of several distributions that can address the issue of infected animal clustering and the dependencies among the branch points. The binomial distribution incorporates the assumption of sampling with replacement, which is appropriate when working with large populations. A model was constructed to estimate the probability that one or more undetected infected breeding swine from undetected infected herds could be selected for export to the US.

The model is a multi-level binomial where each level is a binomial probability distribution conditioned on the prior level. Dependency is incorporated into the model from left to right in the scenario tree. Each branch point on the right is dependent on the branch point to its left. APHIS considered a simple, single-level, binomial distribution to be an inadequate model for this process because it cannot address the two levels of selection required for the model, i.e., the selection of one or more breeding herds for export and the selection of one or more animals from each breeding herd for export. In addition, the model is also able to account for the clustering within herds of animals selected for export and the similar clustering of infected animals within herds. The multilevel binomial probability distribution has been used to evaluate the predictive value of diagnostic testing [47], to validate disease surveillance programs [48], and to evaluate the probability of success or failure of disease eradication programs [49]. Its use has been proposed to evaluate the level of sanitary risk associated with the importation of animals and animal products [50].

Generally, a binomial distribution is useful for evaluating the probability of a specified outcome from a number of independent trials when only two outcomes are possible. For this assessment, one outcome is the selection and export of a healthy animal not infected

with CSF; the other is the export of a CSF-infected animal. The selection process represents the independent trials.

An endpoint of the analysis is the probability that one or more infected breeding swine is selected for export from an infected breeding swine herd, resulting in an incursion of CSF into the US. Results are expressed also as the inverse of this probability, which represents the expected frequency of at least one incursion in a given number of years or the mean time between incursions. The latter value is reported for consistency, since it is used routinely by APHIS decision-makers.

The initiating event is the request to export live breeding swine to the US. Branch point 1 represents the probability of selecting an infected herd for export of breeding swine. Branch point 2 represents the probability of selecting an infected animal, given that an infected herd has been selected.

Derivation of the Mathematical Model

Given that undetected CSF exists in EU regions that might be expected to export breeding swine, the multi-level binomial distribution is derived as follows:

Selection at the herd level

Let **g** = the number of infected breeding herds with undetected CSF in the EU. (Eq. A)

Let **h** = the total number of breeding herds in the EU. (Eq. B)

Then, **g/h** = the probability that a randomly selected breeding herd has undetected CSF. (Eq. C)

And, (1 - **g/h**) = the probability that a randomly selected breeding herd is CSF-free. (Eq. D)

Animal level

Let **i** = the probability that an animal selected from an infected breeding herd is CSF-infected. (Eq. E)

Then (1 - **i**) = the probability that an animal selected from an infected herd is CSF-free. (Eq. F)

Let **f** = the number of animals selected for export from a given breeding herd. (Eq. G)

Then, combining Eq. F and Eq. G, $(1 - \mathbf{i})^{f}$ = given that the herd is infected, the probability that **f** animals selected for export are CSF free. (Eq. H)

Multiplying Eq. C and Eq. H, $g/h(1 - \mathbf{i})^{f}$ = the joint probability that the selected herd is infected and f animals selected for export are CSF-free. (Eq. I)

Adding Eq. D and Eq. I, $\{(1\text{-}\mathbf{g}/\mathbf{h}) + \mathbf{g}/\mathbf{h}(1 - \mathbf{i})^{f}\}$= the probability that a randomly selected breeding herd is either CSF-free, or that it is infected and all the f animals selected from that herd are CSF-free. (Eq. J)

Shipment/export factors

Let **d** = the number of breeding swine shipments per year. (Eq. K)

Let **e** = the number of breeding herds per shipment. (Assume that the number of breeding herds per shipment is constant., i.e., 1. This assumption is discussed subsequently.)(Eq. L)

Then **de** = the number of breeding herds selected for export per year. (Eq.M)

Risky period

Let **b** = the number of weeks that CSF infection remains undetected in the EU in a typical year. (Eq. N)

Then, assuming that breeding swine shipments are randomly distributed throughout the year, multiplying Eq. M by Eq. N and dividing by the number of weeks in a year, **deb**/52 = the number of breeding swine herds selected for shipment during the "risky period," i.e., the length of time in which CSF exists undetected in EU breeding herds in a year. (Eq. O)

Exponentiating Eq. J by Eq. O, $\{(1\text{-}\mathbf{g}/\mathbf{h}) + \mathbf{g}/\mathbf{h}(1 - \mathbf{i})^{f}\}^{(\mathbf{deb}/52)}$ = the probability that all **deb**/52 herds from which animals are selected for export during the risky period are CSF-free herds or, if the herd selected is CSF-infected, the shipment contains only CSF-free animals. (Eq. P)

Subtracting Eq. P from 1, $1 - \{(1\text{-}\mathbf{g}/\mathbf{h}) + \mathbf{g}/\mathbf{h}(1 - \mathbf{i})^{f}\}^{(\mathbf{deb}/52)}\}$ = the complement of Eq. P = the probability that one or more infected animals from one or more infected herds is exported from the total **deb**/52 selected during the risky period. (Eq. Q)

More simply stated, equation Q is the annual probability of exporting one or more CSF infected breeding swine.

Input Values Assigned to Variables for the Breeding Swine Model

The following values were input parameters for the breeding swine model:

g Number of eligible CSF-infected, undetected breeding farms eligible to supply animals for export to the US.

$g= 0.5$

In the two-year period from 1997 and 1998, only one breeder farm located outside of established restriction zones in the EU and providing animals for export became infected with CSF [12, 51-57]. Dividing one farm by 2 years yields a value of 0.5, the annual average number of undetected breeding farms in the EU during the period of The Netherlands outbreak and reflects data from The Netherlands.

h Number of EU breeding herds eligible for export.

APHIS calculated the number of breeding herds (**h**) that could provide exports to the US for each EU Member State being regionalized [8, 57]. APHIS then summed values for each Member State to estimate a total number of EU breeding herds that could provide exports. Since the number of breeding swine operations and the number of farrowing operations differ for each Member State, APHIS used a discrete distribution to weight data for each Member State. Specifically, APHIS calculated the number of breeding swine operations that could provide exports to the US (export-approved breeding operations) as a proportion of the number of farrowing operations in that member state.

Since APHIS was unable to obtain precise data from each Member State for the number of EU breeding operations that could provide exports to the US, we extrapolated from data provided by The Netherlands and comparative information for other Member States that was provided by EU technical staff [57]. The proportion representing The Netherlands was calculated by dividing a uniform distribution (1,100 to 1,200 export-likely breeding herds) by the total number of farrowing operations (6,604) in The Netherlands.

EU experts provided comparative data for other Member States [58]. These estimates were based on (compared with) the proportion calculated for The

Netherlands. EU experts indicated that the proportion applicable to Belgium and The Netherlands [1100 to 1200)/6604] was the same, but that the value should be reduced by 50 percent for Germany and France and reduced by 90 percent for Spain, Italy, Portugal, and Austria. Greece was not considered in this calculation, since it does not export breeding swine.

This corrected proportion was multiplied by the number of farrowing operations in the corresponding Member State. The EU provided the following data for the number of farrowing operations: The Netherlands = 6,604 (value repeated from above); Spain = 201,000; Belgium = 4,841; Germany = 51, 841, Italy = 23,139; Portugal = 59,400; Greece = 9,016; Austria = 0; France = 32,688. Multiplication of the total number of farrowing operations for each Member State by the proportion of export-likely breeding operations in that Member State and summing the results for all Member States yielded a mean value of 14,290. This value is provided for illustration, since the entire distribution was actually used in the model.

b Number of weeks that CSF remains undetected or uncontrolled in EU breeding herds per year, i.e., the "risky period."

b = The number of weeks CSF infection remains undetected in the EU (the "risky period") varies from one Member State to another, as well as over time, within each Member State [8]. APHIS defines it as the time from initiation of infection to the time exports cease, based on the assumption that there is no infection and no risk prior to time of initiation of infection or after exports cease.

Using the data provided by the EU and in close consultation with EU officials, risky periods for EU CSF outbreaks in 1997 are estimated to be: (1) The Netherlands, 35 days; (2) the Lerida province in Spain, 53 days; (3) Segovia, Madrid, and Toledo provinces in Spain, 7 to 21 days, most likely 10 days; (4) Belgium, 42 days; (5) Italy, 21 days; (6) Germany, 7 to 21 days, most likely 10 days. These data were fitted to distributions for each region for which a risky period was defined. As suggested by the values presented above, point distributions were assigned to regions with a single value, i.e., The Netherlands, the Lerida province, and Belgium. Triangular distributions (minimum, maximum, most likely) were assigned to the three Spanish provinces assessed as a unit (Segovia, Madrid, and Toledo), Italy, and Germany.

These values based on the above distributions for variable **b** for each Member States or province listed above were entered as parameter values into @RISK's discrete probability distribution function. Data on the time period for each Member State were weighted (multiplied) by the number of breeding swine operations in each

Member State (see discussion of input variable **h** for data on numbers of breeding swine operations).

d Number of breeding swine shipments per year.

d = 34

Import records for shipments of breeding swine from EU Member States that the US considers to be CSF-free indicated that the US received 34 shipments containing approximately 1,300 breeding swine during 1997 [59]. For purposes of this analysis, APHIS assumed that the export statistics for that portion of the EU being considered for regionalization would roughly approximate the export statistics from Member States previously recognized as free. Therefore, we used the shipment statistics from CSF-free Member States that were documented for 1997 (see Table 2) as an estimate of the export statistics expected for the area of the EU being regionalized.

Table 2. Number of Shipments and Number of Animals in Each Shipment Exported to the US in 1997.

Member State	Number of Shipments	Total Number of Swine
Denmark	9	1,116
Finland	2	12
Sweden	3	23
United Kingdom	20	148
Total	34	1,299

e Number of breeding herds per shipment.

e = 1

APHIS assigned this value based on data available from the UK and Denmark. Import records showed that most shipments from these Member States originated from a single herd [59]. APHIS was unable to obtain specific information for other Member States, so we assumed for this assessment that the number of breeding herds represented per shipment was 1.

f Number of animals selected for export from any given breeding herd.

The data for 34 shipments (Table 2, above) were presented as a distribution considered appropriate to data obtained from APHIS import records [59]. The distribution for the number of swine per shipment was very skewed (analysis performed by C. Chioino, Program and Policy Development, Risk Analysis Systems, APHIS, [59]). The maximum number of animals per shipment was 437, and the minimum number was 1. Most shipments consisted of between 1 and 10 animals. The geometric mean of this distribution is 6.125. APHIS staff used a value of 6 for this assessment.

This stability of this assumption was tested by varying the input parameters. Results of the analysis are presented in Appendix I.

i Probability that an individual animal is CSF-infected, given that the herd is CSF-infected.

i = Triangular distribution (0.05, 0.15, 0.40).

Based on technical advice from EU experts, APHIS used the triangular distribution [60] in its initial quantitative assessment. However, US industry experts suggested that the value could be much more variable, i.e., 25-100% [61]. To evaluate the effect of using diverse estimates, APHIS conducted sensitivity analyses, the results of which are reported in Section I: Sensitivity Analysis.

Simulation Results of the Breeding Swine Model

One endpoint of the breeding swine model analysis is the probability that one or more infected breeding swine is selected for export from an infected breeding swine herd and that the selection results in an incursion into the US. APHIS assumes that the infected animal enters the US and initiates an outbreak. Results are expressed also as the inverse of this probability, which represents the expected span of time in years for at least one incursion to occur.

The initial risk estimates are reported as the minimum, maximum, mean (average), mode (most likely), and median (50th percentile) values of the distributions. APHIS presents the mode and median as preferable to, but also for comparison with, the mean. Mode and median are generally considered a better representation of the central tendency of the distribution than the mean when the distributions are skewed, as they are in this assessment.

Results are expressed also as the inverse of this probability, which represents the expected frequency of at least one incursion in a given number of years.

Results Summary

	Probability of one or more incursions per year	Expected frequency of incursions in years (expect at least one every "x" years)
Minimum	9.78×10^{-6}	1.02×10^{5}
Most likely	$\mathbf{2.97 \times 10^{-5}}$	$\mathbf{3.37 \times 10^{4}}$
Maximum	2.05×10^{-4}	4.88×10^{3}
Mean	5.98×10^{-5}	1.67×10^{4}
Median	4.20×10^{-5}	2.38×10^{4}

In the initial assessment, the most likely expected incursion frequency was at least one (one or more) incursion every 33,670 years.

Swine Semen Model

The objective of this assessment was to estimate the probability that undetected CSF-infected swine semen would be exported from the EU and enter the US. The mathematical model was the same as the breeding swine model. However, definitions and input values changed to reflect the fact that this model estimates risk associated with semen samples rather than individual animals and semen collection centers rather than breeding herds.

Import Assumptions for the Initial Assessment

APHIS assumes that there are possible consequences from undetected CSF in swine semen centers during a risky period in that portion of the EU being regionalized.

APHIS assumes that the risk assessed reflects mitigating influences of current EU legislation. EU legislation defines specific biosecurity procedures for swine semen donors intended to mitigate risk of disease transmission among and within Member States by this pathway [19]. The observation that only a single CSF outbreak occurred in an export-oriented EU-approved swine semen center whereas 103 outbreaks were observed in the general population outside of any restriction zones [8] suggests that the EU regulations had a mitigating effect even during the outbreak in The Netherlands. However, like the breeding

swine model, the input variables for the assessment also incorporate data from that severe outbreak.

APHIS assumes that the incubation period for CSF is 40 days. This value is chosen for consistency with OIE guidelines [26]. APHIS uses this value to define a mitigation measure, i.e., a 40-day holding period for boars after semen collection in addition to the 30-day holding period currently required by EU legislation. APHIS defines this holding period as beginning prior to shipment of semen but after completion of the 30-day isolation period for required for boars before entering the center. APHIS assumes that holding boars for 40 days provides an adequate period of time to observe clinical signs of disease and detect CSF if boars were exposed prior to semen collection.

APHIS assumes that, because of their economic value, donor boars would be closely supervised in the collection center. Therefore, it is likely that any sign of poor health would be detected.

APHIS assumes that a shipment of semen of originates from a single donor boar from a single semen center.

APHIS assumes that a single importation of semen from an infected donor (incursion) will result in an outbreak.

Swine Semen: Scenario Tree and Mathematical Model

The binomial distribution is equally appropriate for the breeding swine and swine semen models. For the swine semen model the two alternatives are selection/export of CSF-free semen from a healthy donor boar and selection/export of CSF-infected semen.

The multi-level binomial is used because the identification of boars for export of semen involves two levels of selection: first, one or more semen collection centers are selected. Second, one or more donor boars are selected from each collection center. A simple, single-level, binomial distribution is inadequate to model this process.

Figure 5 shows a scenario tree describing the pathway for importation of CSF into the US in swine semen. The three-branch-point scenario tree illustrates the underlying APHIS thought process for this model. In this tree, the initiating event is the EU request to export swine semen to the US. Branch point 1 represents the probability of selecting an infected semen center. Branch point 2 indicates the probability of selecting an infected boar. Branch point 3 represents mitigation provided by observing donors for clinical signs during a proposed

40-day holding period after semen collection. The effect of observing the animals clinically during the 40-day holding period (Branch point 3) is assessed as a mitigating factor.

The endpoint of the assessment is the probability that one infected swine semen sample is selected for export from an infected collection center, resulting in an incursion if CSF into the US. Results are expressed also as the inverse of this probability, i.e., the expected frequency of at least one incursion in a given number of years.

Derivation of the Mathematical Model

Given that undetected CSF exists in EU swine semen centers located in the region under consideration and that might export semen to the US, the model is derived as follows:

Selection at the swine semen center level

Let **g** = the number of undetected, CSF-infected swine semen centers. (Eq. A)

Let **h** = the total number of swine semen centers in the region. (Eq. B)

Then, **g/h** = the probability that a randomly selected swine semen center has undetected CSF (Branch Point 1). (Eq. C)

And (1 - **g/h**) = the probability that a randomly selected swine semen center is CSF-free (Eq. D)

Selection at the animal level

Let **i** = the probability that an individual donor boar in an infected semen center is CSF-infected (Branch Point 2). (Eq. E)

Then, (1 - **i**) = the probability that a randomly selected donor boar is CSF-free. (Eq. F)

Let **f** = the number of donor boars selected for semen export from any given semen center. (Eq. G)

Then, combining Eq. F and Eq. G, $(1 - \mathbf{i})^{\mathbf{f}}$ = given (starting with) an infected center, the probability that f donors selected from that infected center are CSF-free. (Eq. H)

Multiplying Eq. C and Eq. H, $g/h(1 - \mathbf{i})^f$ = the joint probability that the center is infected and the f donors selected for export of semen from an infected semen center are CSF-free.
(Eq. I)

Adding Eq. D and Eq. I, $\{(1-\mathbf{g}/\mathbf{h}) + \mathbf{g}/\mathbf{h}(1 - \mathbf{i})^f\}$ = the probability that a randomly selected swine semen center is either CSF-free, or that, if it is infected, all donor boars selected from that center are CSF-free. (Eq. J)

Shipment factors

Let **d** = the number of swine semen shipments per year. (Eq. K)

Let **e** = the number of swine semen centers per shipment. (Eq. L)

Then **de** = the number of swine semen centers selected for export per year. (Eq.M)

Risky period

Let **b** = the number of weeks that CSF infection remains undetected in EU swine semen centers per year (the risky period). (Eq. N)

Then, assuming that swine semen shipments are randomly distributed throughout the year, multiplying Eq. M by Eq. N and dividing by the number of weeks in a year, **deb**/52 = the number of swine semen centers contributing to semen shipments during the risky period.
(Eq. O)

Exponentiating Eq. J by Eq. O, $\{(1-\mathbf{g}/\mathbf{h}) + \mathbf{g}/\mathbf{h}(1 - \mathbf{i})^f\}^{(\mathbf{deb}/52)}$ = the probability that all **deb**/52 swine semen centers selected for the export of semen during the risky period are CSF-free, or, if they are CSF infected, all of the f boars selected as donors are CSF-free. (Eq. P)

Subtracting Eq. P from 1, $1 - \{[(1-\mathbf{g}/\mathbf{h}) + \mathbf{g}/\mathbf{h}(1 - \mathbf{i})^f]^{(\mathbf{deb}/52)}\}$ = the complement of Eq. P = the probability that among the **deb**/52 centers selected for export of semen during the risky period, one or more infected semen donor boars is selected for export from one or more undetected infected centers. (Eq. Q)

More simply stated, equation Q is the annual probability of importing one or more CSF-infected swine semen shipments.

Input values for equation variables

The following values were input parameters for the swine semen model:

g Number of undetected CSF-infected semen centers supplying semen for export.

g = 0.5

In the 2-year period from 1997 to 1998, only one EU approved swine semen center outside of established protection and surveillance zones and providing semen for export became infected with CSF [8, 57]. The value of 0.5 is the average annual number of undetected semen centers in the EU during this period. This 2-year period was chosen as a source of data representing conditions from the extremely severe outbreak in The Netherlands, since there were no undetected infected semen centers in other Member States.

h Number of swine semen centers.

h = 138

The EU identified 138 approved swine semen centers in the Member States [62]. They were distributed as follows: 6 in The Netherlands, 43 in Spain, 11 in Belgium, 1 in Luxembourg, 27 in Germany, 6 in Italy, 3 in Portugal, 0 in Greece, 5 in Austria, and 36 in France. Importation from France, which APHIS considered to be CSF-affected at the time, was allowed under special conditions designed to mitigate risk. These conditions included on-site APHIS inspection of export procedures and testing [5].

b Number of weeks infection remains undetected in EU semen centers per year, i.e., the risky period:

b = the length of the risky period varies from one Member State to another as well as within each Member State [8].

Individual risky periods for EU CSF outbreaks in 1997 are estimated as (a) The Netherlands, 35 days; (b) the Lerida province in Spain, 53 days; (c) Segovia, Madrid, and Toledo provinces in Spain, 7 to 21 days, most likely 10 days (d) Belgium, 42 days; (e) Italy, 21 days; (f) Germany, 7 to 21 days, most likely 10 days. Distributions (triangular or point) were assigned to the risky period for each of the

provinces or Member States as discussed for variable **b** for the breeding swine model.

The values and appropriate distributions for variable **b** for each Member State or province were entered as parameter values into @RISK's discrete probability distribution function. Data for each risky period listed above were weighted (multiplied by) a factor representing the number of swine semen centers in the corresponding Member State or province (see variable **h** above for data on the number of swine semen centers).

d Number of semen shipments per year:

d = 53

APHIS import records [59] were used to estimate the number of doses of EU swine semen per Member State that may be imported into the US. The estimates were based on import data from EU Member States that the US had previously declared to be CSF-free and Canada. Canada was included as a country that contains EU genetic material in its livestock and because of the need for data providing reasonable estimates of doses of swine semen that the US might import. Input values were derived from the number of shipments from CSF-free Member States and Canada between 1994 and 1998.

In 1994, the US imported 700 doses of swine semen from Denmark. In 1995, the US imported 781 doses of swine semen from France. In 1996, 1997, and 1998, the US imported 2,596; 689; and 581 doses, respectively, of swine semen from the UK. In 1994, 1995, 1996, 1997, and 1998, the US imported 735; 742; 864; 965; and 132 doses, respectively, of swine semen from Canada.

APHIS assumed that there would be no significant difference in average number of shipments from CSF-free Member States and Canada and the average number of shipments per Member State from the EU region requesting regionalization. Based on its documented import statistics, APHIS estimated the number of doses imported to be zero, 800, and 2,600 for minimum, most likely, and maximum values, respectively. In terms of US exports of swine semen, a typical shipment might be 10-30 straws, representing one or two boars, a shipment of 15 doses is not unusual [63]. The most likely number of shipments annually is, therefore, 800/15 = 53.

e Number of swine semen centers per shipment:

In the model, the number of semen centers from which semen is exported during the risky window is defined as **a*e**, where **a** is the number of swine semen shipments multiplied by the proportion of risky weeks in a year (a=db/52), and **e** is the number of semen centers per shipment. APHIS assumed that **a*e** = 1. The assumption was derived from VS import records indicating that most of the exports to the US from Denmark and the UK originated from a single company, i.e., the Pig Improvement Corporation in the UK and Danmark Corporation in Denmark [59].

Based on the assumption that **a*e** = 1, the value for **e** may then be calculated as 1/**a**. In turn, **a** is calculated using the formula **a = (d*b)/52** which incorporates the length of risky time period (**b**), the number of breeding swine shipments per year (**d**), and the number of weeks in a year (52).

f Number of boars selected per semen center per shipment.

f = 1

As previously mentioned, a typical shipment might contain 10-30 straws, representing one or two boars [63]. APHIS used a value of one boar per center per shipment.

i Probability that an individual animal is CSF-infected, given that the semen center is infected.

i = Triangular distribution (0.05, 0.15, 0.40)

The triangular distribution was suggested by EU technical experts [60]. However, US industry experts suggested that the value could be much more variable, i.e., 25-100% [61]. To evaluate the effect of using diverse estimates, APHIS conducted sensitivity analyses, the results of which are reported in Section I: Sensitivity Analysis.

Simulation Results of the Swine Semen Model

One endpoint of the analysis is the probability that one or more infected semen shipments are selected for export from an infected semen center, which represents an incursion into the US. Results are expressed also as the inverse of this probability, and are reported as the expected span of time in years for at least one incursion (outbreak) to occur.

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The initial quantitative risk estimates for import of swine semen are reported as the minimum, maximum, mean (average), mode (most likely), and median (50th percentile) values of the distributions. APHIS presents mean, mode and median for comparison. Results are expressed also as the inverse of this probability which represents the expected frequency of at least one incursion in a given number or years.

Results Summary

	Probability of one or more incursions per year	Expected frequency of incursions in years (at least one expected every "x" years)
Minimum	1.90×10^{-4}	5.63×10^{3}
Most likely	**5.43×10^{-4}**	**1.84×10^{3}**
Maximum	1.44×10^{-3}	6.94×10^{2}
Mean	7.25×10^{-4}	1.38×10^{3}
Median	6.91×10^{-4}	1.45×10^{3}

In the initial assessment, the most likely expected incursion frequency was at least one incursion in 1,842 years. This value reflected input data from the extremely severe outbreak in The Netherlands and was considered a relatively conservative estimate of risk. However, APHIS also performed an analysis in which it varied several input parameters to estimate how sensitive the results were to variations in input parameter values. Results of the sensitivity analyses are reported in Section I: Sensitivity Analysis.

Mitigated Swine Semen Model

APHIS assessed the mitigating effect of a 40-day post-collection quarantine of semen donors during which the animals would be observed clinically before their semen could be used.

A mathematical model based on a binomial distribution was developed to estimate the mitigating effect of this quarantine.

Derivation of the Mathematical Model

Let **m** = the probability that a CSF-infected boar will show clinical signs sufficient to allow diagnosis within the 40 day quarantine. (Eq. A)

Then **(1-m)** = the probability that a CSF-infected boar will not show clinical signs sufficient to result in diagnosis. (Eq. B)

Let **k** = the number of infected donor boars held for observation. (This equation does not assume that all boars held for observation are CSF-infected. Thus, k does not necessarily equal the total number of boars held for observation.) (Eq. C)

Then, exponentiating Eq. B by Eq. C, $\mathbf{(1\text{-}m)^k}$ = the probability that some k infected boars will not show clinical signs allowing diagnosis. (Eq. D)

Subtracting Eq. D from 1, $\mathbf{1 - (1\text{-}m)^k}$ = the complement of Eq. D = the probability that one or more boars will show clinical signs allowing diagnosis. (Eq. E)

Input values for equation variables

m Probability that a CSF-infected boar will have clinical signs sufficient to allow diagnosis during quarantine.

A uniform distribution with a minimum value of 0.7 and a maximum value of 0.8 was used [64].

k Number of donor boars for export held for clinical observation.

This value was set to 1, based on the assumption that semen is collected from a single animal held alone. Setting k = 1 also excludes the possibility of a sentinel effect from several animals held with the shipment donor.

Results Summary

	Probability of one or more incursions per year	Expected frequency of incursions (at least one expected every "x" years)
Minimum	4.33×10^{-5}	2.31×10^{4}
Most likely	$\mathbf{1.24 \times 10^{-4}}$	$\mathbf{8.09 \times 10^{3}}$
Maximum	4.11×10^{-4}	2.43×10^{3}
Mean	1.81×10^{-4}	5.52×10^{3}
Median	1.72×10^{-4}	5.81×10^{3}

Adding a 40-day holding period and clinical observation reduced the most likely estimate for CSF incursion by swine semen into the US from every 1,842 years to one in approximately 8,090 years, indicating that the mitigation step is very effective.

Pork Model

This model employs a multilevel binomial probability approach based on conditional probabilities. APHIS assesses both the probability that contaminated meat would enter the US (an incursion, reflecting a release assessment) and the probability that ingestion of contaminated pork by pigs in the US would result in an outbreak (reflecting an exposure assessment).

In this assessment, APHIS models pork as a single aggregate commodity. Therefore, the approach does not address possible differences in risk that might be associated with different pork products such as bacon, pigs' feet, or prime cuts. However, at this point, APHIS has no information to suggest that disaggregation, i.e., assessing levels of risk for individual pork products, is necessary.

Import Assumptions for the Initial Assessment

APHIS assumes that the primary pathway for exposure of US domestic livestock to CSF is feeding of contaminated food waste to swine.

Dissemination of imported food commodities within the US food marketing system and the collection and disposal pathways for food waste are extremely complex. APHIS simplifies this by assuming that every restaurant box of imported pork is a statistically independent entity that can transmit CSF to domestic swine.

APHIS assumes that all swine slaughtered to produce pork for export to the US from the EU comply with EU regulations for the control and eradication of CSF and that pork intended for export to the US is produced using EU standard operating procedures.

APHIS assumes that if a CSF-infected animal is slaughtered, all of the meat from that animal is contaminated with virus. This assumption increases the probability of a CSF outbreak.

APHIS assumes that the disease risk from imported pork used by households is negligible because food waste from households is rarely if ever collected by waste feeders. Therefore,

the model reflects the probability that waste fed to pigs was collected only from restaurants and institutions.

APHIS assumes that any ingestion of infected imported pork by any single domestic pig will result in an outbreak.

Pork: Scenario Tree and Mathematical Model

Figure 6 shows a scenario tree describing the primary pathway by which APHIS believes contaminated pork would be exported to the US. The initiating event is the slaughter of pigs. Branch point 1 represents the probability that any slaughtered pig is contaminated with CSF. Branch point 2 represents the probability that imported pork is used by restaurants. Branch point 3 represents the probability that restaurants discard uncooked pork trimmings in their waste materials. Branch point 4 represents the probability that a swine producer collects waste material from restaurants and institutions. Branch point 5 represents the probability that the waste feeder does not cook the waste product containing imported pork sufficiently. Branch point 6 represents the probability that the swine producer feeds inadequately cooked waste containing CSF-contaminated pork to swine.

<u>Derivation of the Mathematical Model</u>

Let **Q** = the number of pigs slaughtered to provide pork for export to the US.

Let **P** = the probability that a given pig is CSF-infected.

Then **Q x P** = the number of CSF-infected pigs slaughtered to provide pork for export.

Let **N** = the number of boxes of infected pork produced from a slaughtered pig supplied to restaurants and institutions in the US.

Then **Q x P x N** = the number of CSF-contaminated boxes of pork.

Let **F2** = the fraction of imported pork used by restaurants and institutions.

Then **Q x P x N x F2** = the number of CSF-infected boxes of pork used by restaurants and institutions.

Let **F3** = the probability that a box is trimmed by restaurants and institutions and the trimmings put in waste uncooked.

Let **F4** = the probability that waste from a restaurant or an institution is collected by a waste feeder.

Let **F5** = the probability that a waste feeder does not cook waste adequately to kill CSF virus.

Let **F6** = the probability that CSF-contaminated waste fed to swine causes an outbreak.

APHIS calculated the probability that imported CSF-infected (inadequately cooked) waste causes one or more outbreaks of CSF per year as:

$$\mathbf{P(x) = 1-\{[1-(F3 \times F4 \times F5 \times F6)]^{(Q \times N \times P \times F2)}\}.}$$

<u>Input values for equation variables</u>

Q Number of pigs slaughtered to provide pork for export to the US.

Q is a variable derived from the expected quantity of pork imports and the quantity of pork obtained from the slaughter of a single pig. The derivation is as follows:

APHIS first estimated the quantity of pork that is likely to be obtained from the slaughter of a single pig [65]. The quantity of pork meat per animal (in pounds) was assigned a triangular distribution with a minimum value of 150 pounds, most likely value of 160 pounds, and maximum value of 170 pounds.

The proportion of meat from an exported animal was assigned a triangular distribution with a minimum value of 0.35, a most likely value of 0.4, and a maximum value of 0.45 [65]. The product of these distributions estimates the quantity of pork meat (in pounds) exported per hog. The resulting value is multiplied by 0.454 to convert pounds into kilograms.

P Probability that a pig imported from the EU is infected with CSF.

P is a variable derived mathematically as follows:

Let P_1 = the number of CSF-infected undetected swine fattening farms outside of established EU restriction zones in 1997. P_1 = 101 [8].

Let P_2 = the total number of swine fattening farms in that part of the EU being regionalized. P_2 = 719,447. P_2 includes 15,784 farms in The Netherlands, 100,000 in

Spain, 8,201 in Belgium, 187,475 in Germany, 256,412 in Italy, 79,900 in Portugal, 14,433 in Greece, and 57,272 in France [58].

Then P_1 / P_2 = the probability that a randomly selected fattening farm had undetected CSF in 1997.

Let P_3 = the probability that a randomly selected animal resides on an undetected CSF- infected fattening farm. P_3 was described as a triangular distribution with minimum value of .05, most likely of .15, and maximum of .40 [64].

Let P_4 = the probability that a randomly slaughtered animal from a farm with undetected CSF in 1997 was shipped during the risky period. P_4 is equal to the length in days of the risky period (see discussion of breeding swine model, variable **b,** for explanation), divided by 365.

Then **P** = $\mathbf{(P_1 / P_2) \times P_3 \times P_4}$ = the probability that a randomly selected EU slaughter pig is CSF-infected at the time of slaughter.

N Number of infected restaurant boxes obtained from each slaughtered pig.

A triangular distribution with a minimum value of 4, most likely of 7, maximum of 8 was used [65].

The proportion of infected waste that contains an infectious dose of virus from a single animal was described as a triangular distribution with a minimum value of 0.9, a most likely value of 0.95, and a maximum value of 1 [65]. This distribution of the infected proportion of meat was multiplied by the distribution for the number of restaurant boxes exported per slaughtered pig.

F2 Fraction of imported pork used by restaurants of institutions.

A triangular distribution with minimum value of 0.30, most likely value of 0.40, and maximum value of 0.50 was used [66].

F3 Probability that restaurants or institutions discard uncooked trimmings.

Pork industry representatives informed APHIS that the fraction of pork trimmed by restaurants is small or very nearly zero because restaurant pork is cut and packaged so as to eliminate the need for further trimming. A triangular distribution with a

minimum value of 0.00001, most likely value of 0.0001, and maximum value of 0.001 was used to describe this information [65].

F4 Probability that restaurant waste is collected by waste feeders.

This probability was estimated from data suggesting that 2,666 restaurants supply food scraps to waste feeders. Census Bureau data for 1992 indicate that there are approximately 430,000 restaurants in the US, excluding Hawaii and Alaska. Therefore, the probability waste from a given restaurant is collected by waste feeders was estimated as 2,666 / 430,000 = 0.006. A triangular distribution with a minimum value of 0.005, most likely value of 0.006, and maximum value of 0.007 is used [67].

F5 Probability that waste feeder does not cook waste sufficiently to inactivate CSF virus.

APHIS assigned individual distributions to licensed and unlicensed waste feeder operations to estimate the probability that a waste feeder operation does not cook waste sufficiently to inactivate CSF virus. APHIS used a triangular distribution with a minimum value of 0.4, most likely value of 0.5, and a maximum value of 0.8 for licensed waste feeders was provided by APHIS staff [65]. Since unlicensed waste feeders would feed waste products to swine illegally, APHIS assumed waste from these sources would not be cooked sufficiently. Therefore, APHIS assigned a value of 1 to unlicensed feeders.

The distributions for waste feeders were weighted (multiplied) by the proportion of the total that was licensed or unlicensed. APHIS estimated a triangular distribution with a minimum value of 0.9, most likely value of 0.95, and a maximum value of 0.98 for licensed feeders [65]. This distribution was multiplied by the probability distribution for inadequate cooking by licensed waste feeders.

APHIS defined unlicensed waste feeders as one minus the triangular distribution for licensed feeders. The resulting distribution was multiplied by 1 for the probability that unlicensed waste feeders do not cook waste sufficiently to inactivate CSF virus.

The parameter F5 was also adjusted for the proportion of infected waste that may contain CSF virus. The distributions for licensed and unlicensed waste feeders were multiplied by a triangular distribution representing a proportion with a minimum value of 0.9, a most likely value of 0.95, and a maximum value of 1 [65]

F6 Probability that feeding uncooked CSF-infected waste results in a disease outbreak.

APHIS staff assumed that if uncooked food waste containing CSF virus is fed to pigs, the probability of causing CSF in the pigs is as high as 100%. For this assessment a point probability of 1 was estimated.

Simulation Results of the Pork Model

The input value for volume of pork used in this assessment was based on benchmarks developed using US pork imports from Denmark as a reference value to estimate import quantities from various countries (Germany, Italy, Spain, The Netherlands, France, Portugal, Austria and Belgium-Luxembourg) [67]. These benchmarks provide an estimate of import quantities that might be expected from EU countries in the absence of sanitary restrictions but are characterized by a significant degree of uncertainty. Sensitivity analyses, the results of which are reported in Section I: Sensitivity Analysis, were conducted to address the uncertainty associated with these estimates.

Results Summary

	Probability of one or more incursions per year	Expected frequency of outbreaks (expect at least one incursions per "x" years)
Minimum	3.48×10^{-7}	2.87×10^{6}
Most likely	$\mathbf{4.41 \times 10^{-5}}$	$\mathbf{2.27 \times 10^{4}}$
Maximum	7.70×10^{-4}	1.30×10^{3}
Mean	4.80×10^{-5}	2.08×10^{4}
Median	3.19×10^{-5}	3.13×10^{4}

In the initial assessment, the most likely expected incursion frequency was at least one incursion in 22,700 years.

Consequence assessment

Should CSF be introduced into the US, the consequences would be significant. Not only would the costs of eradication be extremely high, but the cost in trade would be significant. For reference, the cost of the 1976 eradication program in 1997 dollars was $525 million.

However, the estimates reported in this assessment suggest that the risk of importation with breeding swine and pork is quite low. Risk from swine semen with mitigation (40 day quarantine with clinical observation) is also quite low. Therefore, in accordance with the

OIE guidelines which state that consequence assessment is not necessary if the risk associated with release and/or exposure is low [21], APHIS did not calculate the precise economic impact of biological consequences.

Risk estimation

APHIS feels that the risks estimated here are conservative, and that they over-estimate the risk. APHIS cites several reasons for this. First, although the estimates reflect EU control mechanisms that are defined in legislation and binding on Member States, some of the input values for these estimates incorporate data from the severe epidemic that occurred in The Netherlands and other Member States in 1997 and 1998. APHIS believes that the situation in The Netherlands was unique. In this regard, no other Member State had an epidemic that severe at that time, and none (including The Netherlands) has had one since.

Furthermore, APHIS believes that the epidemic provided a learning experience for the EU. In this regard, it should be significantly less likely that an epidemic of that magnitude would occur in The Netherlands or any other Member State of the EU today because of the lessons learned during that epidemic.

Breeding swine and swine semen

Current US restrictions on breeding swine and swine semen importation imposed to protect against swine diseases other than CSF may further mitigate risk from these sources. These restrictions, which are defined in import protocols negotiated by the US and the EU, include quarantine and testing for brucellosis, pseudorabies, and tuberculosis. Theoretically, the quarantine requirements for these diseases could also provide mitigation for CSF since animals are observed by a veterinary official of the exporting country during the quarantine period. However, these export conditions were not considered in the risk assessment. APHIS chose not to consider them because requirements concerning these diseases could be changed independently of the restrictions regarding CSF, and changes might not be appropriate for CSF.

Fresh/frozen pork

EU swine intended as a source of pork for export to the US are also subject to additional mitigations that are not addressed in this report. Specifically, swine are slaughtered in compliance with the requirements of the Food Safety and Inspection Service (FSIS). These requirements include ante- and post-mortem inspection, which should provide additional mitigation. Although the impact of this was not addressed in the assessment, APHIS believes that the FSIS requirements can further reduce the risk that infected pork will be exported.

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Summary

The level of risk estimated in the initial analysis for all three models is summarized in Table 3. Sensitivity analyses on all three models, the results of which are reported in Section I: Sensitivity Analysis, suggest that these estimates are relatively stable, at least in relation to the variations assessed for specific input parameters.

Table 3. Risk Estimate Summary for Importation of Breeding Swine, Swine Semen and Fresh or Frozen Pork into the US from the EU

	Values from Initial Assessment		*Mitigated Values*	
Model	Probability = Q (incursions per year)[3]	Frequency =1/Q (years)[4]	Probability = Q (incursions per year)[3]	Frequency = 1/Q (years)[4]
Breeding swine[1]	2.97×10^{-5}	33,670	Not reported	Not reported
Swine semen[2]	5.43×10^{-4}	1,842	1.24×10^{4}	8,090
Pork[1]	4.41×10^{-5}	22,676	Not reported	Not reported

[1]Mitigations were not assessed for breeding swine and pork since the probability calculated from the initial assessment was extremely low.

[2]Mitigating effects of holding semen donor boars for 40 days after collection of semen and observing them for clinical signs were assessed.

[3]Probability was assessed as the likelihood of one or more incursions per year (most likely value). Variability and uncertainty, including estimated maximum and minimum values, are described in the report. Results are reported to four significant figures. These reflect the actual values calculated. Expression to four significant figures is not intended to imply a high level of precision.

[4]Frequency is assessed as the expected mean time between incursions or the expectation that there would be at least one incursion (one or more) within the number of years reported (most likely value). Variability and uncertainty, including estimated maximum and minimum values, are presented in the report. Results are reported to four significant figures. These reflect the actual values calculated. Expression to four significant figures is not intended to imply a high level of precision.

The risks estimated for the breeding swine and pork models are low. For that reason, APHIS did not assess the effect of additional mitigations on the initial risk estimates for these models. Therefore, no mitigated values are reported.

The initial risk estimated for swine semen was significantly higher than that for the other models. This difference reflected the fact that the prevalence of infected semen centers as a proportion of the total population, based on data from The Netherlands, exceeds that of infected breeding herds. Therefore, the effects of a 40-day holding period after semen collection during which donor animals were observed for clinical signs were assessed.

Mitigation options

APHIS is considering imposing some or all of the following conditions in order to ensure that contaminated material is not exported from the EU:

1. Swine and swine semen will be accompanied by a certificate of origin verifying that the animals have not lived in a CSF-affected region.

2. Animals will be prohibited from transiting a CSF-affected region unless they were moved to their destination in a sealed conveyance.

3. Animals will be prohibited from commingling with swine that have been in a CSF-affected region.

4. Equipment or materials used to transport the swine or donor boars will be prohibited for use in transporting animals ineligible for export to the US unless the vehicles are appropriately cleaned and disinfected.

In its assessment, APHIS considered an additional mitigation applicable to semen donors, which reduced the risk from those donors significantly:

5. Following the collection of semen, donor animals could be subjected to clinical observation during a quarantine period that is sufficient for animals to develop clinical signs (40 days).

This quarantine would occur in addition to the 30-day isolation currently required in EU legislation. The additional mitigation was extremely effective at reducing the risk of introducing CSF in swine semen. Although a 30-day period is currently specified in EU regulations, the additional 40-day period with clinical observation is not.

6. Animals could be tested serologically for evidence of CSF at various stages of the pathway.

Although the mitigating effects of serological testing were not reported here, this option is available should a need for additional mitigations be perceived.

Limitations of the Analysis

This report describes the results of a risk assessment regarding potential imports of EU breeding swine, swine semen, and fresh and frozen pork. The hazard of interest is the introduction into and establishment of CSF in the US.

The analysis reflects the influence of US and EU legislation in place intended to mitigate the risk of transmission of swine diseases through swine and swine products. Should any of these regulations change, the results of this assessment might not apply.

The analysis depends primarily on data submitted by the EU for 1997-1998. Should epidemiological characteristics of CSF in the EU change significantly, the results of this assessment might not apply.

The analysis does not consider spatial and temporal aspects of disease transmission from CSF-infected regions. Those issues are addressed subsequently in the supplemental assessment.

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* Most unpublished references are available at http://www.aphis.usda.gov/vs/reg-request.html. Copies of documents not available there may be requested from Dr. Gary Colgrove, by telephone at (301) 734-8363 or by mail at Unit 38, 4700 River Road, Riverdale, MD 20737.

Figure 1. Member States of the European Union

Section I

Figure 2. Geographic Scope of the Risk Assessment

Germany

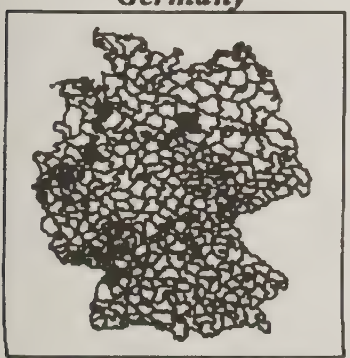


Figure 2a

Italy

Figure 2b

"Black regions" identified as unacceptable for export during the course of the intitial assessment

Germany: Kreis Altmarkkreis Salzwedel, Kreis Heinsberg, Kreis Oldenberg, Kreis Vechta, Kreis Warendorf

Italy: The Island of Sardinia, Local Health Unit No. 11 Vercelli within the region of Piemont and Province/Local Health Unit of Parma in the region of Emilia-Romagna

Figure 2a

Germany - Black Regions

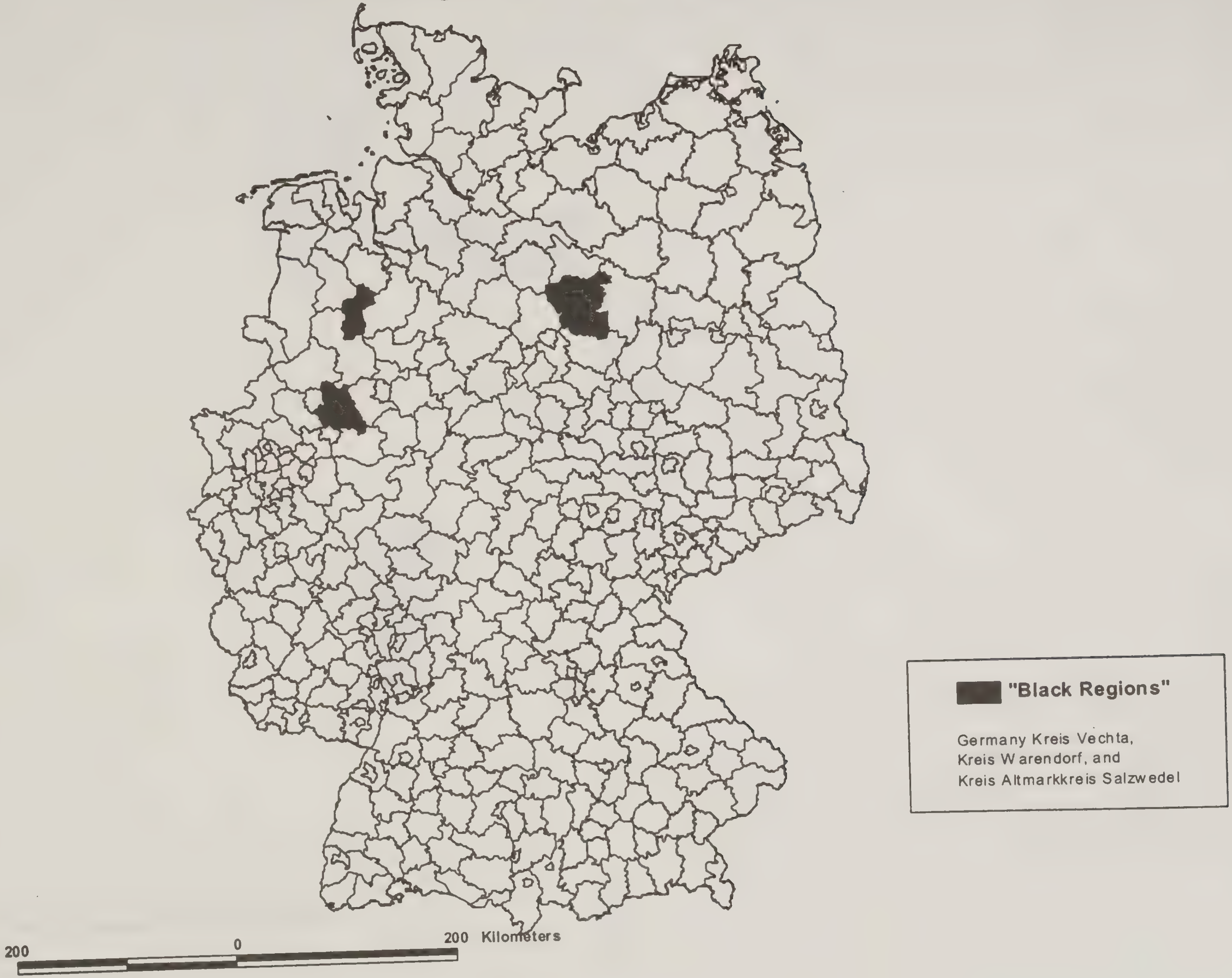


Figure 2b
Italy - Black Regions

Figure 2b
Italy - Black Regions

Figure 3. EU Member States Where Infected Herds Were Found outside of Protection and Surveillance Zones during the 1997-98 Outbreaks

Figure 4. Scenario tree of the pathway for potential importation of CSF into the United States - breeding swine model.

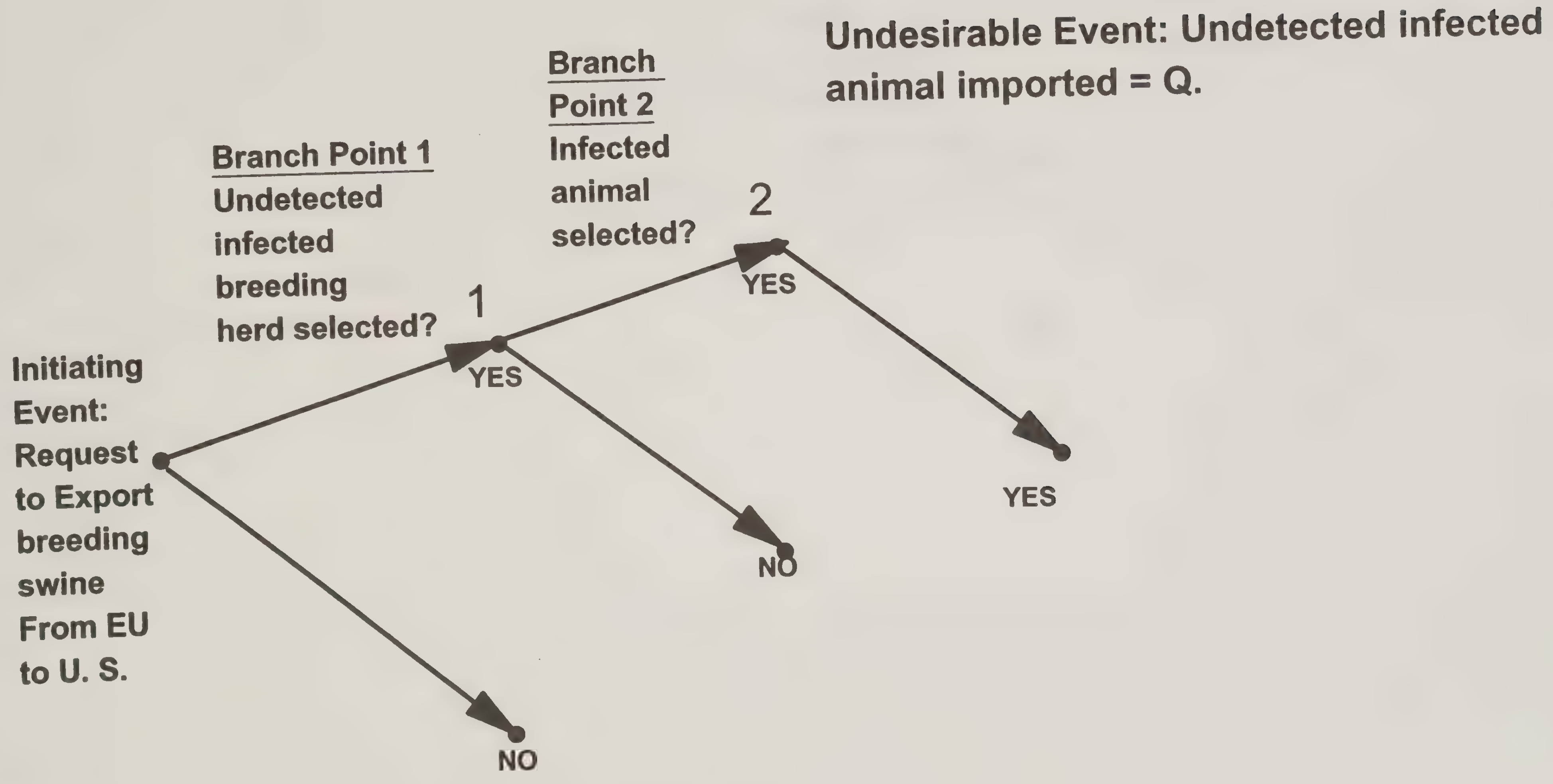


Figure 5. Scenario tree of the pathway for potential importation of CSF into the United States - swine semen model.

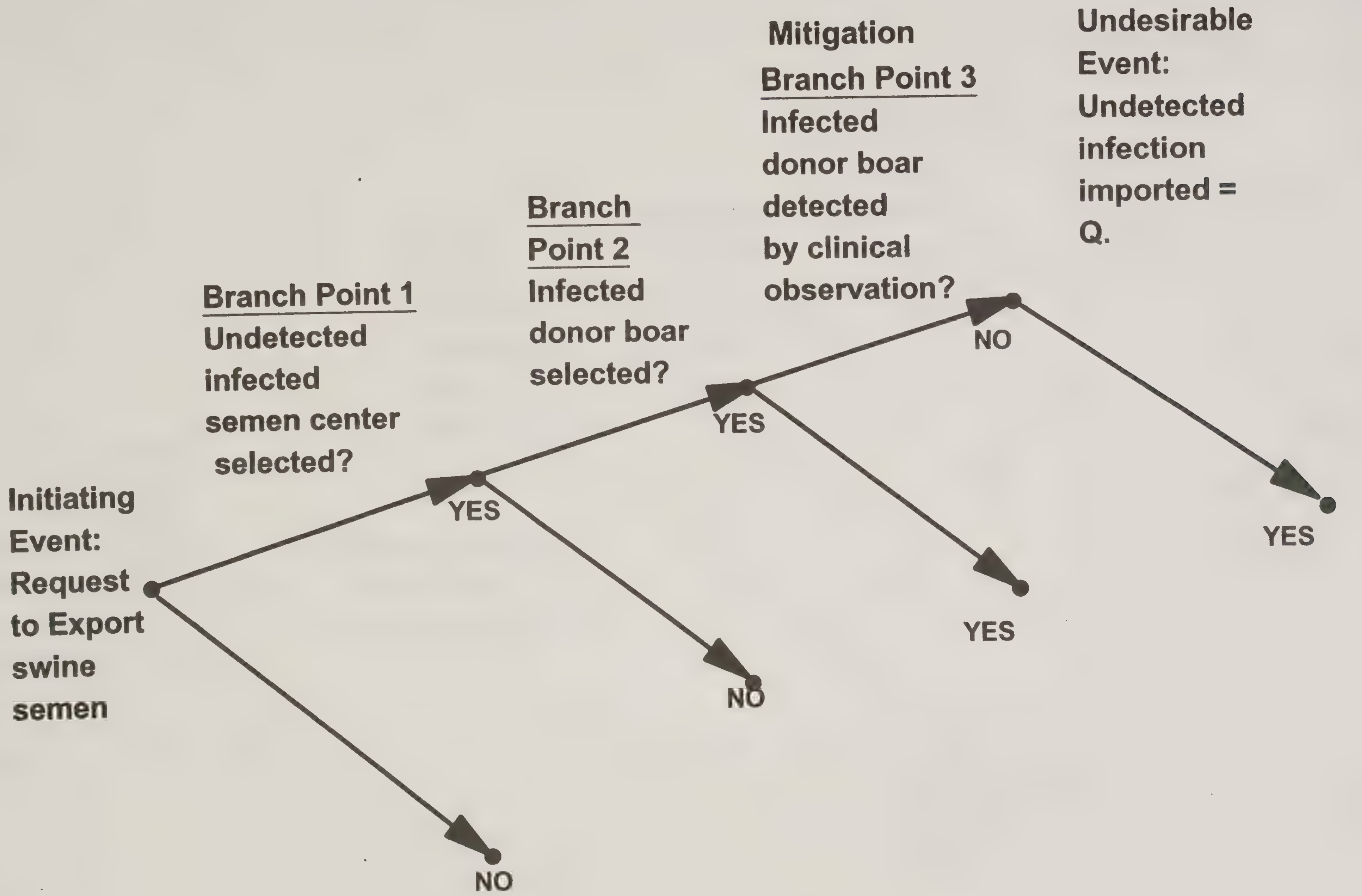
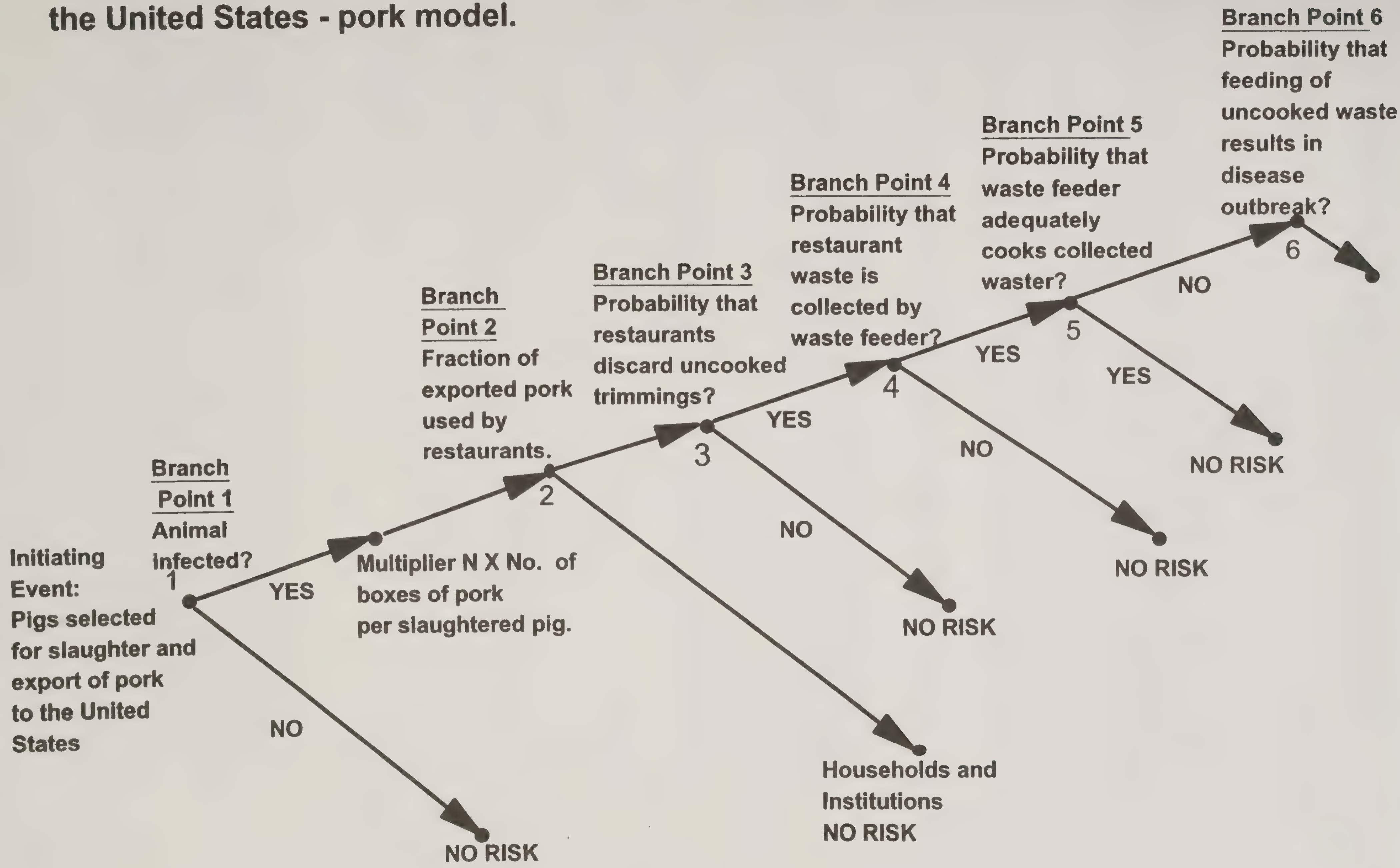


Figure 6 - Scenario tree of the pathway for potential importation of CSF into the United States - pork model.



Section I: Sensitivity Analysis: Risk Analysis for Importation of Classical Swine Fever Virus in Swine and Swine Products from the European Union
December 2000

Sensitivity Analysis

Introduction

Input values for several parameters were varied in each model (breeding swine, swine semen, and pork) to assess the stability of the results reported in the initial analysis. However, not all values were varied in each model. The model in which the value was varied is indicated in parenthesis.

a = Number of swine semen shipments per year.

e = Number of swine semen centers per shipment (mitigated and unmitigated swine models).

f = Number of animals selected for export from any given breeding herd (breeding swine and swine semen models).

g = Number of eligible CSF-infected, undetected breeding farms or semen centers supplying animals for export to the US and **h** = Number of EU breeding herds or semen centers eligible for export (breeding swine and swine semen models) expressed as **g/h**.

h = Total number of breeding herds or swine semen centers eligible for export in the EU.

i = Probability that an individual animal or semen shipment is CSF-infected, given that the herd or semen center is CSF-infected.

Breeding Swine Model

In the initial analysis for breeding swine,

e = 1; f = 6, **g** = 0.5, **h** = 14,290 (i.e., the mean value for the distribution used in the initial analysis); and **i** = triang(0.05, 0.15, 0.40).

Effect of varying the number of animals selected for export (f)

For this sensitivity analysis,

f = 38

This input value represents the arithmetic mean of the number of breeding swine shipments (see Table 2 and associated discussion in the initial analysis), rather than the geometric mean (**f** = 6). For the initial analysis, a geometric mean was chosen as the most appropriate to represent the skewed nature of the data. For the sensitivity analysis, APHIS used the arithmetic (simple average), rather than the geometric mean. This variation allows input of the total number of animals actually estimated from the data, i.e., 34 shipments averaging 38.2 animals for a total of 1,299 animals.

Results Summary

	Probability of one or more incursions per year		Expected frequency (expect at least one incursion every "x" years)	
	Initial Analysis	Sensitivity Analysis	Initial Analysis	Sensitivity Analysis
Minimum	9.78×10^{-6}	2.81×10^{-5}	1.02×10^{5}	3.56 x 104
Most likely	$\mathbf{2.97 \times 10^{-5}}$	$\mathbf{4.63 \times 10^{-5}}$	$\mathbf{3.37 \times 10^{4}}$	$\mathbf{2.16 \times 10^{4}}$
Maximum	2.05×10^{-4}	2.21×10^{-4}	4.88×10^{3}	4.51×10^{3}
Mean	5.98×10^{-5}	8.42×10^{-5}	1.67×10^{4}	1.19×10^{4}
Median	4.20×10^{-5}	5.74×10^{-5}	2.38×10^{4}	1.74×10^{4}

In this scenario, the expected frequency of incursion was increased from one or more in 33,700 years to one or more in 21,600 years. Increasing the number of breeding swine per shipment in the manner described resulted in less than a twofold increase in risk, which appears to constitute a minimal effect.

Effect of varying the proportion over time of infected breeding swine farms exporting to the US (g/h)

g = 1

h = 14,290*2

Input values for **g** and **h** in the initial analysis were selected from data generated during the EU CSF situation during the 1997/98 outbreak in The Netherlands in order to provide a risk estimate reflecting the worst outbreak in EU history. Since g in this scenario has been defined as one outbreak per 2 years, it may also be expressed as 0.5. Please note that

$$\frac{\mathbf{g}}{\mathbf{h}} = \frac{0.5}{14{,}290} = \frac{1}{14{,}290*2}$$

Therefore, in this analysis,

g = 0.5 and **h** = mean value of 14,290 or g = 1 and h = (mean of 14,290*2). These numbers could be used to calculate a point estimate for **g/h**. However, APHIS felt that using a point estimate for the ratio did not address adequately the degree of uncertainty associated with the ratio. To account for the uncertainty, the ratio was expressed as a beta distribution, and the variables, g and **h** were entered into the model as Beta(g+1, h-g+1).

Results Summary

	Probability of one or more incursions per year		Expected frequency (expect at least one incursion every "x" years)	
	Initial Analysis	Sensitivity Analysis	Initial Analysis	Sensitivity Analysis
Minimum	9.78×10^{-6}	1.07×10^{-6}	1.02×10^{5}	9.35×10^{5}
Most likely	**2.97×10^{-5}**	**4.45×10^{-5}**	**3.37×10^{4}**	**2.25×10^{4}**
Maximum	2.05×10^{-4}	1.23×10^{-3}	4.88×10^{3}	8.12×10^{4}
Mean	5.98×10^{-5}	1.19×10^{-4}	1.67×10^{4}	8.43×10^{3}
Median	4.20×10^{-5}	7.64×10^{-5}	2.38×10^{4}	1.31×10^{4}

In this scenario, the expected frequency of incursion was increased from one or more in 33,670 years to one or more in 22,500 years. However, the results reported do reflect uncertainty associated with the revised input values in the form of the beta distribution. Uncertainty is seen by the increased range between the maximum and minimum values in the sensitivity analysis (incursion frequency ranging from one or more in 88,200 to 935,000 years) in comparison to the initial analysis (incursion frequency ranging from one or more in 4,880 to 102,000 years). Spread for the values of incursion frequency in the sensitivity analysis approximates 850,000 years in comparison to approximately 97,000 years for the initial analysis, an almost ninefold increase in range.

*Effect of varying the probability that an animal in a CSF-infected herd is CSF-infected **(i)***

The initial input values for **i** were based on a triangular distribution (0.05, 0.15, 0.40) suggested by EU officials [1]. Industry representatives from the US suggested a slightly different triangular distribution (0.05, 0.30, 1.00) [2]. This analysis is based on the values suggested by US industry representatives. They reported a most likely range of 25-30 percent, but suggested that the value could be as high as 100 percent. APHIS chose to use the 30 percent value to provide a more conservative estimate of risk.

Results Summary

	Probability of one or more incursions per year		Expected frequency (expect at least one incursion every "x" years)	
	Initial Analysis	Sensitivity Analysis	Initial Analysis	Sensitivity Analysis
Minimum	9.78×10^{-6}	1.08×10^{-5}	1.02×10^{5}	9.29×10^{4}
Most likely	$\mathbf{2.97 \times 10^{-5}}$	$\mathbf{3.82 \times 10^{-5}}$	$\mathbf{3.37 \times 10^{4}}$	$\mathbf{2.64 \times 10^{4}}$
Maximum	2.05×10^{-4}	2.21×10^{-4}	4.88×10^{3}	4.53×10^{3}
Mean	5.98×10^{-5}	7.74×10^{-5}	1.67×10^{4}	1.29×10^{4}
Median	4.20×10^{-5}	5.35×10^{-5}	2.38×10^{3}	1.87×10^{4}

In this scenario, the expected frequency of incursion was increased from one or more in 33,670 years to one or more in 26,000 years, only a 1.3-fold change.

Swine semen model

In the initial analysis for breeding swine,

e = 1/a; f = 1, **g** = 0.5, **h** = 138, and **i** = triang(0.05, 0.15, 0.40).

Effect of varying the number of infected semen centers for export (seven- year period to estimate prevailing risk)

Values for **g/h** were varied in the same way as they were for the breeding swine model. In this case, however, the value for **h** differs. As before,

$$\frac{\mathbf{g}}{\mathbf{h}} = \frac{0.5}{138} = \frac{1}{138*2}$$

In this sensitivity analysis, risk was estimated using data covering the entire period between implementation of the Single Market Program in the EU. The date of implementation (1992) was chosen because it represented the starting date of the new EU open border policy under which animals, people, goods and services could move freely among Member States. APHIS felt that data collected under the conditions in existence before the borders opened would not be comparable or relevant.

A value of 7 years was used to represent the period from implementation in 1992 (effectively 1993 to early 2000). Although two approved swine semen centers became infected during the outbreak involving The Netherlands, only one was exporting [3].

Taken together, these data suggested that APHIS might expect that one semen center might be infected in a 7-year period.

Therefore, in the sensitivity analysis,

g = 1.0 and **h** = 138*7, reflecting the total number of opportunities for exporting semen over the 7-year period, i.e., the number of semen centers in the EU that could be infected in a year multiplied by the 7-year period under consideration. To reflect uncertainty about the ratio of **g/h**, the numerical ratio defined here was replaced with a beta distribution Beta(g+1, h-g+1).

Use of the Beta distribution in these circumstances requires that two assumptions be made. The first is that each semen center has the same probability of becoming infected. The second is that each center has only one opportunity per year to become infected. APHIS considers this to reflect a conservative approach. If one considers multiple opportunities per year, the denominator (**h**) increases, and risk declines substantially.

Results Summary

	Probability of one or more incursions per year		Expected frequency (expect at least one incursion every "x" years)	
	Initial Analysis	Sensitivity Analysis	Initial Analysis	Sensitivity Analysis
Minimum	1.90×10^{-4}	4.74×10^{-6}	5.63×10^{3}	2.11×10^{5}
Most likely	$\mathbf{5.43 \times 10^{-4}}$	$\mathbf{2.63 \times 10^{-4}}$	$\mathbf{1.84 \times 10^{3}}$	$\mathbf{3.80 \times 10^{3}}$
Maximum	1.44×10^{-3}	2.76×10^{-3}	6.94×10^{2}	3.62×10^{2}
Mean	7.25×10^{-4}	4.08×10^{-4}	1.38×10^{3}	2.45×10^{3}
Median	6.91×10^{-4}	3.18×10^{-4}	1.45×10^{3}	3.14×10^{3}

In this scenario, the expected frequency of incursion was reduced from one or more in 1,840 to one or more in 3,800 years. Therefore, the risk is reduced by a factor slightly more than 2.

The increase in uncertainty is seen in the extended range of the distribution. Range in the initial analysis goes from one or more incursions in 694 years to 5,630 years (a difference of less than 5000 years) to range between 362 years and 211,000 (a difference of more than 210,000 years). Range is therefore increased by a factor of more than 40.

Section I: Sensitivity Analysis: Risk Analysis for Importation of Classical Swine Fever Virus in Swine and Swine Products from the European Union December 2000

Effect of varying the number of infected semen centers exporting semen to the US (one year period to maximize risk)

APHIS wished to assess the risk under conditions that were even more extreme than those in the 1996/1997 outbreak. Therefore, APHIS assessed risk using the hypothesis that an approved semen center approved by the EU for export to the US would become infected with CSF every year. We should point out that there are no data to support this hypothesis.

In this sensitivity analysis, **g** = 1.0 and **h** = 138*1.

In this analysis, a point estimate, rather than a distribution, was used as the input value for **g/h.** APHIS considered a distribution to address uncertainty to be unnecessary since the assumptions reflected a situation worse than there were data to support.

Results Summary

	Probability of one or more incursions per year		Expected frequency (expect at least one incursion every "x" years)	
	Initial Analysis	Sensitivity Analysis	Initial Analysis	Sensitivity Analysis
Minimum	1.90×10^{-4}	3.80×10^{-4}	5.63×10^{3}	2.63×10^{3}
Most likely	$\mathbf{5.43 \times 10^{-4}}$	$\mathbf{1.10 \times 10^{-3}}$	$\mathbf{1.84 \times 10^{3}}$	$\mathbf{9.10 \times 10^{2}}$
Maximum	1.44×10^{-3}	2.88×10^{-3}	6.94×10^{2}	3.47×10^{2}
Mean	7.25×10^{-4}	1.45×10^{-3}	1.38×10^{3}	6.90×10^{2}
Median	6.91×10^{-4}	1.38×10^{-3}	1.45×10^{3}	7.23×10^{2}

In this scenario, the expected frequency of incursion was increased from one or more in 1,800 years to one or more in 910 years, or by a factor of approximately 2. Therefore, hypothesizing a scenario worse than that seen in the outbreak in The Netherlands did not affect the risk to a large extent.

Effect of varying the probability that an animal in a CSF-infected center is CSF-infected (i)

In this sensitivity analysis, i = triang(0.05, 0.30, 1.00), to reflect estimates provided by US industry representatives.

Results Summary

	Probability of one or more incursions per year		Expected frequency (expect at least one incursion every "x" years)	
	Initial Analysis	Sensitivity Analysis	Initial Analysis	Sensitivity Analysis
Minimum	1.90×10^{-4}	2.03×10^{-4}	5.63×10^{3}	4.92×10^{3}
Most likely	$\mathbf{5.43 \times 10^{-4}}$	$\mathbf{1.11 \times 10^{-3}}$	$\mathbf{1.84 \times 10^{3}}$	$\mathbf{9.03 \times 10^{2}}$
Maximum	1.44×10^{-3}	3.59×10^{-3}	6.94×10^{2}	2.78×10^{2}
Mean	7.25×10^{-4}	1.63×10^{-3}	1.38×10^{3}	6.13×10^{2}
Median	6.91×10^{-4}	1.53×10^{-3}	1.45×10^{3}	6.52×10^{2}

In this scenario, the expected frequency of incursion was increased from one or more in 1,800 years to one or more in 903 years, or by a factor of approximately 2.

Effect of varying the number of swine semen centers per shipment (e)

In this sensitivity analysis, APHIS assumes that each shipment comes from a different center, setting variable **e** = 1. This is in contrast to the initial assessment in which a value for **e** is set based on the assumption that only one boar from one center could be selected for export during the risky window. This sensitivity analysis was intended to relax the restrictions imposed by this assumption by allowing semen to originate from multiple boars from multiple centers, a revision that should increase the level of risk.

Results Summary

	Probability of one or more incursions per year		Expected frequency (expect at least one incursion every "x" years)	
	Initial Analysis	Sensitivity Analysis	Initial Analysis	Sensitivity Analysis
Minimum	1.90×10^{-4}	2.60×10^{-4}	5.63×10^{3}	3.84×10^{3}
Most likely	$\mathbf{5.43 \times 10^{-4}}$	1.14×10^{-3}	$\mathbf{1.84 \times 10^{3}}$	$\mathbf{8.81 \times 10^{2}}$
Maximum	1.44×10^{-3}	1.08×10^{-2}	6.94×10^{2}	9.30×10^{1}
Mean	7.25×10^{-4}	2.49×10^{-3}	1.38×10^{3}	4.01×10^{2}
Median	6.91×10^{-4}	1.73×10^{-3}	1.45×10^{3}	5.78×10^{2}

In this scenario APHIS might expect one or more incursions in 1,800 years using the initial values and one or more incursions in approximately 880 years in the second. Therefore, risk is increased by a factor of approximately 2.

Mitigated Swine Semen Model

The input values for **g/h**, **i**, and **e** were varied in a sensitivity analysis to assess the effects on risk estimates:

Effect of varying the number of infected centers exporting semen to the US (g/h)

In this sensitivity analysis, the values **g** = 1.0, **h** = 138*7 were entered into a beta distribution to assess the degree of uncertainty associated with the estimates.

Results Summary

	Probability of one or more incursions per year		Expected frequency (expect at least one incursion every "x" years)	
	Initial Analysis	Sensitivity Analysis	Initial Analysis	Sensitivity Analysis
Minimum	4.33×10^{-5}	1.09×10^{-6}	2.31×10^{4}	9.21×10^{5}
Most likely	$\mathbf{1.24 \times 10^{-4}}$	$\mathbf{4.94 \times 10^{-5}}$	$\mathbf{8.09 \times 10^{3}}$	$\mathbf{2.03 \times 10^{4}}$
Maximum	4.11×10^{-4}	8.37×10^{-4}	2.43×10^{3}	1.19×10^{3}
Mean	1.81×10^{-4}	1.03×10^{-4}	5.52×10^{3}	9.75×10^{3}
Median	1.72×10^{-4}	7.85×10^{-5}	5.81×10^{3}	1.27×10^{4}

In this scenario, the expected frequency of incursion was decreased from one or more in 8,090 years to one or more in 20,300 years. This reduced the estimated risk by more than twofold.

Effect of varying the number of swine semen centers per shipment

In this sensitivity analysis, as in the unmitigated model, APHIS assumes that each shipment comes from a different center, setting variable **e** = 1. This is in contrast to the initial assessment in which a value for e is set based on the assumption that only one boar from one center could be selected for export during the risky window. This sensitivity analysis was intended to relax the restrictions imposed by this assumption by allowing semen to originate from multiple boars from multiple centers, a revision that should increase the level of risk.

Results Summary

	Probability of one or more incursions per year		Expected frequency (expect at least one incursion every "x" years)	
	Initial Analysis	Sensitivity Analysis	Initial Analysis	Sensitivity Analysis
Minimum	4.33×10^{-5}	5.46×10^{-5}	2.31×10^{4}	1.83×10^{4}
Most likely	$\mathbf{1.24 \times 10^{-4}}$	$\mathbf{3.55 \times 10^{-4}}$	$\mathbf{8.09 \times 10^{3}}$	$\mathbf{2.81 \times 10^{3}}$
Maximum	4.11×10^{-4}	2.93×10^{-3}	2.43×10^{3}	3.41×10^{2}
Mean	1.81×10^{-3}	6.22×10^{-4}	5.52×10^{3}	1.61×10^{3}
Median	1.72×10^{-4}	4.30×10^{-4}	5.81×10^{3}	2.33×10^{3}

In this scenario, the expected frequency of incursion was decreased from one or more in 8,090 years to one or more in 2,810 years. This increased the estimated risk by less than a factor of 3.

Pork Model

Sensitivity analysis of the pork model is presented as three simulations. The results reported are those from the initial analysis as well as two additional volumes of exported pork. One of the additional volumes is higher than that used in the initial analysis, and one is lower. The higher and lower volumes were selected on the basis of economic "benchmarks" developed by APHIS, VS, Centers for Epidemiology and Animal Health (CEAH). These are derived from the total export history of each EU Member State, and the data were transformed using Denmark as an index case.

Data representing Denmark were chosen for the transformation because Denmark is the EU Member State recognized by USDA as CSF-free which exports the largest amount of pork. In the transformation, the total volume of exports is multiplied by the ratio: Denmark's exports of fresh and frozen pork to the US/Denmark's total fresh and frozen pork exports.

Summary Results for Low Volume Pork Imports

	Probability of one or more outbreaks per year	Expected frequency of outbreaks (expect at least one outbreak every "x" years)
Minimum	2.11×10^{-7}	4.74×10^{6}
Most likely	$\mathbf{4.41 \times 10^{-6}}$	$\mathbf{2.27 \times 10^{5}}$
Maximum	2.82×10^{-4}	3.55×10^{3}
Mean	2.42×10^{-5}	4.13×10^{4}
Median	1.61×10^{-5}	6.21×10^{4}

Summary Results for the Initial Analysis

Minimum	3.48×10^{-7}	2.87×10^{6}
Most likely	$\mathbf{4.41 \times 10^{-5}}$	$\mathbf{2.26 \times 10^{4}}$
Maximum	7.70×10^{-4}	1.30×10^{3}
Mean	4.80×10^{-5}	2.08×10^{4}
Median	3.19×10^{-5}	3.13×10^{4}

Summary Results for the High Volume Scenario

Minimum	8.53×10^{-7}	1.17×10^{6}
Most likely	$\mathbf{1.19 \times 10^{-4}}$	$\mathbf{8.40 \times 10^{3}}$
Maximum	1.23×10^{-3}	8.13×10^{2}
Mean	7.12×10^{-5}	1.40×10^{4}
Median	4.84×10^{-5}	2.07×10^{4}

The expected incursion frequency of the low volume of pork exports (one or more in 227,000 years) was approximately 10% of that of the initial analysis (one or more in 22,600 years). The expected incursion frequency of the high volume of pork exports (one or more in 8,403 years) was less than threefold greater.

Sensitivity Analysis Summary

None of the sensitivity analyses tested for this assessment (variations in **a**, **e**, **f**, **g/h** and **i**) affected the frequency of disease incursion to a major extent. The maximum effect, either as an increase or decrease in incursion frequency was a factor of 3. The majority of effects constituted increases or decreases in disease incursion frequency by a factor of 2 or less.

However, increasing the level of uncertainty by assigning beta distributions as input values for **g** and **h** greatly extended the range between maximum and minimum values for the incursion frequency of the breeding swine and swine semen models. In this assessment, ranges in these model results were increased by nine and fortyfold, respectively.

Section I: Sensitivity Analysis: Risk Analysis for Importation of Classical Swine Fever Virus in Swine and Swine Products from the European Union December 2000

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Section II. Spatial and Temporal Considerations

Introduction

In June 1999, APHIS assessed the risk of importing CSF in swine and swine products from the EU [1]. A revision of this analysis is provided in Section I. The purpose of this supplement is to describe, with the aid of geographic data, the spatial and temporal patterns of CSF outbreaks throughout the EU since 1997.

Animal demographics and movement patterns of animals and CSF in the EU are described in relationship to one another in order to identify potential risk factors for the exportation of breeding swine, swine semen, and fresh pork to the US. The patterns assessed were:

(1) shipment patterns of live swine and products in the EU, (2) geographic distribution of domestic swine populations (including breeding swine) and semen collection centers, (3) geographic distribution of wild boar populations, (4) known CSF infections in wild boar populations, (5) temporal trends in extent of CSF spread, and (6) patterns of CSF spread in the 1997-1998 epidemic. This information is intended to provide insight into potential risks from EU imports to the US of CSF transmission from wild boar, frequency of CSF outbreaks in domesticated herds, movement of CSF among herds, efficacy of EU control measures, and magnitude of outbreaks in various regions in the EU.

Methods

Data for this supplemental assessment were obtained through official communication with representatives of the EU Commission and individual Member States during a site visit [2], and documents provided by EU officials [3]. The data are organized into thematic geographic data layers using ArcView software [4-6]. The information in the data layers is displayed in geographic units that provide the finest resolution for which the data were readily available. These geographic units are based on various administrative boundaries used in the EU such as provinces, regions, landers, and kreis. In many cases, these units are at a scale equivalent to a US county. In some other cases, the data were only available in units at a scale equivalent to a US state.

The focus of the supplemental assessment was the six EU Member States that have been affected by CSF in since 1997 (Figure 1). These are Germany, the Netherlands, Belgium, Italy[1], Spain, and France [2, 7, 8]. Although France has not experienced CSF outbreaks in domesticated swine in the last 7 years, CSF virus has been detected in a wild boar in a small area of the country adjacent to the German border. A region in Germany is one in which CSF has been a recurring problem in wild boar [9]. Although Austria reported

[1] The Island of Sardinia, though part of Italy, is excluded from this assessment and from consideration as part of the proposed change in US regulations due to continued CSF outbreaks in domestic swine originating from wild boar as well as the presence of African Swine Fever.

diagnosis of disease in a single wild boar in November 2000 [66, 67], the outbreak occurred after data were collected for this analysis, and, at the time of this writing, there were no reports of transmission to domestic swine. For the remainder of the Member States in which CSF has not occurred since at least 1997 data are aggregated to a national level.

As previously discussed (see footnote Section I, page 12) the UK is not included in this analysis even though, after a 14-year period of freedom, an outbreak was detected in August 2000. APHIS intends to evaluate the risk from this outbreak separately.

The data are compared descriptively in a graphic format, using these thematic geographic data layers. Four principal comparisons are presented: (1) swine movements among EU Member States are shown relative to the progression of the 1997-98 CSF epidemic in the EU; (2) the approximate geographic locations of potential sources of breeding swine and swine semen exports are shown relative to the locations of wild boar populations, known infections in wild boar, and restricted control areas established in accordance with EC regulations due to the presence of CSF infection in wild boar; (3) the geographic distribution of the domestic swine population is shown relative to the locations of wild boar populations, known infections in wild boar, and restricted areas established due to the presence of CSF infection in wild boar; and (4) the geographic distribution of the domestic swine population is shown relative to the locations of all CSF outbreaks in the EU since 1997.

Where possible, the source of the outbreaks is identified. For example, epidemiologic information from the EU epidemic suggests that some primary outbreaks resulted from direct or indirect contact with wild boar and secondary outbreaks from animal movement or other contacts [7, 10]. Temporal aspects in the extent of disease spread are also considered.

Data and Data Processing

Administrative boundary data were obtained in a shapefile format from ArcEurope (ESRI, Redlands, CA), ArcWorld (ESRI, Redlands, CA), and ESRI Data & Maps (ESRI, Redlands, CA). Boundary and hypsographic data in a vector product format were obtained from Digital Chart of the World (National Imagery and Mapping Agency, Department of Defense, Washington, DC) and converted to a shapefile format using TNTmips software (MicroImages, Corp., Lincoln, NE). Shapefiles were processed and displayed using ArcView software (ESRI, Redlands, CA). Tabular data were created in Lotus Approach and edited using either Approach or MicroSoft Excel software. In each database created, the full name of a country, province, or community was used as a unique identifier, or key field, for accessing information in tables combined through joins or links.

Thematic Layers

The main thematic layers were selected sets of administrative boundaries at primary, secondary, and tertiary levels. In addition, transportation, city, and landmark places were developed as data layers for the geographic extents of each selected boundary. Overlay methods were used to display two or more thematic layers containing information pertaining to risk assessment issues. The Mercator projection was used because of its conformal nature in maintaining local angular relationships among administrative boundaries at the levels used. Distance units are in meters.

Cloropleth Maps

Areal quantitative data were displayed on cloropleth maps. Data values were examined using histograms and then data classes were created based on natural breaks, equal intervals over a range of values, or quantiles. Shades of gray and cross-hatchings were used to show class membership relative to a value range. Layouts were produced showing quantitative information for each administrative area. Layouts were designed for visual orientation and limited comparisons of different areas. Layouts presented in this report were not intended for use in analysis or for drawing conclusions. Other than map layouts of thematic overlays, no other geographic or spatial analysis methods were used in this observational study.

Relationship Between Swine Movements and Spread of CSF

APHIS considered the possibility that patterns of swine movement would correlate with epidemiological pathways defined for swine fever epidemics. To assess this, APHIS identified patterns of swine movements among EU Member States in relationship to disease progression in the 1997-98 CSF epidemic.

The primary outbreak for this epidemic occurred in Paderborn, Germany and was confirmed on January 7, 1997 (Figure 3). The 1997 outbreaks appeared to be linked to infectious material from Germany that contaminated a Dutch lorry. The improperly disinfected truck carried infectious material back to The Netherlands after transporting pigs in the Paderborn area of Germany [7]. In this epidemic, secondary spread occurred through the movement of an empty truck into The Netherlands where additional spread took place from a variety of causes including the movement of swine, people, equipment, and semen for artificial insemination.

Prior to The Netherlands epidemic, no CSF outbreaks had occurred in The Netherlands for 4 years, in Spain for 10 years, and in Belgium for 2 years [7]. The first outbreak in The Netherlands was confirmed on February 4, 1997. The epidemic in the Netherlands peaked in early June 1997. Twenty-six new outbreaks were confirmed in 1 week. The outbreak

ended after a total of 60 weeks, and no new outbreaks were reported after March 1998 (Figure 4). A total of 429 outbreaks occurred in the Netherlands in 1997 and 1998.

Shortly after the virus was detected in The Netherlands, a new outbreak occurred in Italy. The outbreak was confirmed on February 21, 1997 [7]. This outbreak originated from pig imports from the Netherlands. Only two outbreaks in Italy were confirmed (2 days apart) as being associated with The Netherlands epidemic. Other outbreaks that occurred in 1997 were attributed to contact with infected wild boar in Italy (predominantly on the island of Sardinia) or unknown sources [11, 12]. The timeline in weeks for outbreaks on mainland Italy since 1997 is shown in Figure 5.

The epidemic then moved through The Netherlands, Belgium, Italy, and Spain. Epidemiological evidence suggests strongly that CSF was transmitted from the Netherlands to Belgium, Italy, and Spain via the movement of live swine and associated contacts with people and equipment [11-31]. Also consistent with the hypothesis that disease moved with transported swine is the observation that Belgium, Italy, and Spain are the EU Member States receiving the largest quantities of live swine exports from The Netherlands (Figure 2). The data shown in the figure are average exports for 1993-96 [14].

The first two outbreaks in Spain that originated from The Netherlands were confirmed simultaneously on April 17, 1997 [11]. As the epidemic moved into Spain, it peaked very quickly. Fifteen new outbreaks were confirmed the week following confirmation of the first two outbreaks. The epidemic also tailed off quickly but continued for 65 weeks in Spain. No new outbreaks were reported after July 1998 (Figure 6). A total of 99 outbreaks were reported.

Belgium was the last Member State to become infected as part of The Netherlands epidemic. The first outbreak was confirmed there on June 30, 1997 [11]. This outbreak was attributed to person and transport contact with The Netherlands. Only eight outbreaks occurred in Belgium. None was reported after July 1997 (Figure 7).

Many of the outbreaks that occurred in Germany and Italy after 1997 were unrelated to the epidemic in The Netherlands [15]. Germany reported several additional primary outbreaks after 1997. However, secondary spread of most of these was limited. The number of primary and secondary outbreaks in Germany is discussed later in this report. The timeline for these outbreaks is shown in Figure 8.

In Italy, outbreaks originating from wild boar have been predominantly, though not exclusively, confined to the island of Sardinia. The EU recognizes Sardinia as a CSF-infected region. However, no instances of CSF transmission from Sardinia to mainland Italy have been documented [11]. However, Sardinia is excluded from the assessment because it continues to have outbreaks in domestic swine that have originated in wild boar but also because African swine fever is endemic on the island.

These correlative patterns are consistent with the hypothesis that some outbreaks in domestic swine follow animal movement pathways in the EU and show that the extent of disease spread can be extensive. As we will discuss later, the number of outbreaks and extent of spread associated with the pathways in the EU epidemic are greater than those that have been associated with disease originating from infected wild boar.

Relationship of Breeding Swine and Swine Semen Export Origins to Location of Wild Boar Populations

APHIS considered the possibility that breeding swine and swine semen centers located in close proximity to infected wild boar populations might pose a high risk of infection. To address this, APHIS identified the location of breeding swine and swine semen exports (to other Member States in the EU) in relation to the geographic locations of infected wild boar.

In this section, the geographic locations of potential sources of breeding swine and swine semen exports to other Member States and potentially to the US are described relative to locations of wild boar populations, known infections in wild boar, and restricted areas established in accordance with EU regulations due to the presence of CSF infection in wild boar.

Wild boar populations are located throughout Europe. However, not all populations are CSF-infected. Germany and France contain some of the largest populations of wild boar as a whole, estimated as 600,000 and 450,000, respectively [16]. Germany, Italy, France, and Austria have reported CSF infection in wild boar at one time or another since 1995. Germany, Italy, and France reported CSF infection in wild boar in 1998 [17] and Austria in 2000 [66, 67]

Once CSF is detected in wild boar, EU legislation requires that eradication plans for disease be established as part of local contingency plans for surveillance and control [23]. EU legislation requires that LVUs maintain active surveillance and control activities in wild boar affected areas [23]. These plans, developed locally by individual LVUs, generally define protection and surveillance zones appropriate to the local situation. The contingency plan should prohibit trade in wild boar meat, domestic pigs, semen, embryos, or ova; provide for submission of periodic reports to the EU and other Member States; and define a monitoring program to last no less than 12 months after CSF detection. Transport restrictions on domestic materials may be suspended 12 months after last detection or virus in wild boar, and restrictions on transport of wild boar meat may be suspended after 24 months. Plans should define protection and surveillance zones around infected wild boar and restrict movement of domestic animals out of these. Germany, Italy, France, and Luxembourg currently maintain eradication plans and such movement-restricted areas for

CSF infection in wild boar [2, 9, 18-22]. APHIS intends to prohibit exports to the US from regions that the EU has defined as restricted [30].

The presence of infected wild boar is not always geographically associated with disease in domestic pigs. For example, although France has reported CSF infection in wild boar in a small region near the German border, there have been no CSF outbreaks in France attributed to infection in wild boar in the last 7 years [2]. In addition, although CSF infection was reported in wild boar in part of Lower Austria in 1996 and Eastern Austria in 2000 [66, 67], Austria has had no CSF outbreaks in domesticated swine since 1996 [2, 7, 17]. This may reflect the effectiveness of EU disease control measures.

However, in some areas, a history of disease transmission from infected wild boar to domestic swine has been documented. Germany and mainland Italy have had recurring CSF outbreaks in their domesticated swine population due to infection in wild boar. Germany experienced 46 CSF outbreaks in 1997, 11 in 1998, 6 in 1999, and 2 to date in 2000 [24, 25]. Several of these were attributed to contact with infected wild boar. Of interest is that, over time, the number of outbreaks has been reduced significantly. Many of the outbreaks in Germany occurred within restricted areas consisting of protection and surveillance zones established in accordance with EU regulations [23], which may have limited additional spread.

Wild boar are present throughout Germany, though the larger populations appear to be somewhat concentrated in four landers in the northeast and southwest part of the country (Figure 9). These include the landers of Mecklenburg-Vorpommern (Mecklenburg-Western Pomerania), Brandenburg, Hessen, and Rhineland-Pfalz (Rhineland-Palatinate). Of these four landers, the population appears somewhat more concentrated in the northeast in the landers of Mecklenburg-Vorpommern and Brandenburg [15, 26].

Wild boar kill statistics were used to approximate the numbers of wild boar in different areas. The data presented in Figure 9 represent the numbers of wild boar reported shot by hunters in the various kreis (county-equivalent regions) in Germany [26]. As such, they do not necessarily constitute exact population estimates in these kreis, but may give some insight into the relative wild boar populations within the different landers (state-equivalent).

Some breeding swine are exported from these four landers, even though many German breeding swine exports in 1999 originated from areas with smaller wild boar populations in the northern and southern parts of the country (Figure 10 and 11) [15]. Seven of the 27 EU-approved swine semen centers in Germany are located within three of these four landers. Rheinland-Pfalz does not have any approved centers (Figure 12) [15]. Therefore, both swine semen and breeding swine are exported from areas with large populations of wild boar.

As with the breeding swine, many German swine semen exports in 1999 originated in areas with smaller wild boar populations in the northern and southern parts of the country. Of the four landers with the largest wild boar populations, only one, Brandenburg, exported swine semen in 1999 (Figure 12) [15].

Therefore, German exports to other Member States (and potentially to the US) originate from areas both with and without large populations of wild boar. However, effectively, German domestic swine exports do not originate from protection and surveillance areas with movement restrictions in place because of the presence of infected wild boar, since domestic pig movement out of these areas is prohibited by EU legislation [23].

Italy has also reported CSF outbreaks in domestic swine due to infection in wild boar. Outbreaks occurred in mainland Italy in 1996 and 1997. The source of one outbreak in 1998 and three in 1999 in mainland Italy remains unconfirmed, but the virus was reported to be of a similar type as that from the wild boar-related outbreaks in 1996 and 1997 [27, 28].

Italy has six EU-approved swine semen centers. Three of these centers are located in the Region of Lombardia in the north-central part of the country (Figure 13) [29]. The figure shows the region of Lombardia to contain a patchy distribution of wild boar. However, most boar are distributed primarily in the more mountainous areas throughout the rest of the country [30].

Italy reported that it has not exported breeding swine or swine semen to other Member States in 1999 and is generally an importer of such products [31]. Therefore, movement of such products from the country is not an issue at this time. APHIS has no information regarding Italy's plans for export in the future. However, if Italy did intend to export to other Member States or the US, most exports would originate from areas with relatively low density of wild boar.

The Netherlands contains two different populations of wild boar [32]. The first of these is the Veluwe population, Province of Gelderland, located in the east central part of the country. The second is the Meinweg population in the southeastern part of the country. To prevent damage to agricultural crops, both populations are maintained within fences.

While these two populations are geographically separated, their habitat is in close proximity to areas of The Netherlands from which large numbers of breeding swine are shipped, and in which EU approved swine semen centers are located (Figure 14). The Veluwe population was segregated into two parts by closing overpasses over A50, a main road running north and south through The Netherlands, during the 1997 epidemic. The population was also tested for CSF during the epidemic, and virus was not detected [32]. No CSF has been detected subsequently in wild boar in The Netherlands [2, 17]. Therefore, wild boar populations have not constituted a significant pathway in the region.

For Belgium, Figure 15 shows that, in 1999, breeding swine exports originated primarily from one or more collection points in each province. Exports originated primarily from the northern part of the country [31]. EU-approved semen centers in Belgium are also concentrated in the northern part of the country (Figure 16) [29].

In contrast, the wild boar population is concentrated in the southeast part of the country, particularly in the areas of Luxembourg and Namur [33]. No CSF is currently known to exist in the wild boar population in Belgium [2, 17]. Therefore wild boar populations do not appear to constitute a risk at this time.

Wild boar population estimates for other EU Member States, where available, are shown in Table 1 [16].

At this time, epidemiological evidence suggests that presence of infected boar constitutes an issue only in Germany and Italy. This could be a problem anywhere in the EU where CSF remained undetected in the wild boar population. However, EU legislation requires that LVUs establish contingency plans for surveillance and control of disease and prevents export of domestic swine from areas under restriction for CSF in wild boar [23]. Although there are some export sources in those countries, they are not located in areas under EU restrictions because of CSF-infected wild animals.

Relationship Between Domestic Swine and Wild Boar Populations

APHIS considered the possibility that disease transmission from wild boar to domestic animals might be greater in areas containing high densities of both domestic swine and wild boar. In this section, APHIS describes the geographic relationships between domestic swine populations and (a) wild boar populations, (b) locations of known infections in the wild boar, and (c) restricted areas established in accordance with EU regulations due to the presence of CSF infection in wild boar.

The EU provided APHIS with estimates of the distribution of wild boar in various regions within Germany, Italy, France, The Netherlands, and Belgium, as well as available total wild boar population estimates in other Member States [33-34, 40, 44, 50-52]. The EU also provided demographic information on domestic pigs. The period of time for which data were available to describe domestic swine distributions in Member States differs [35-37]. Specifically, for Germany and Belgium, data were only available for 1996; for France, data were available for 1995; for Italy, data were available for 1994; and for Spain, data were available for 1993. While more recent data are available for The Netherlands, 1995 data were used to provide a representation of pre-epidemic swine populations [36-38].

Between 1997 and 2000, only Germany and Italy had CSF outbreaks in domesticated swine that were attributed directly to contact with wild boar [2, 33, 36, 42-45, 52]. For that reason, the subsequent discussion will focus on Germany and Italy.
Domestic swine are present throughout Germany, although somewhat greater numbers are located in the southern part of the landers of Niedersachen (Lower Saxony) and the northern part of Nordhein-Westfalen [36, 38]. Wild boar are also present throughout Germany, though the larger populations appear to be somewhat concentrated in four landers in the northeast and southwest part of the country (Figure 17) in the landers of Mecklenburg-Vorpommern (Mecklenburg-Western Pomerania), Brandenburg, Hessen, and Rhineland-Pfalz (Rhineland-Palatinate). Therefore, there was some (but not a great deal of) concurrence between high density populations of domestic and wild boar.

In mainland Italy (Figure 18) most of the domestic swine are concentrated in the Po Valley area in the Region of Lombardia in the north-central part of the country [36, 38] . The wild boar population is primarily distributed in the more mountainous areas throughout the rest of the country although even in the Region of Lombardia the figure shows a patchy distribution of wild boar in the higher altitudes [34]. The highest densities of wild boar and domestic swine do not appear to coincide to a large extent.

Therefore, in the Member States of most concern because of CSF disease in wild boar, wild boar populations (which may or may not be infected) and domestic pig populations do not coincide to a noticeable extent.

Data from two other Member States with uninfected wild boar are presented for completeness. For example, in Belgium (Figure 19), much of the domestic swine population is concentrated in the northwest part of the country, particularly in the area of West Vlaanderen [36]. The wild boar population, however, is concentrated in the southeast part of the country, particularly in the areas of Luxembourg and Namur [33].

In The Netherlands (Figure 20) the domestic swine population is concentrated in the southern region or Kring. As discussed earlier, there are two different populations of wild boar in the country. The habitats for these two populations are in close proximity to areas of The Netherlands with large concentrations of domesticated swine. Both wild boar populations are maintained within fences [32]; and, as previously mentioned, no CSF infection is currently known to exist in these populations [2, 17].

Relationship Between Domestic Swine Density and CSF Outbreaks

APHIS considered the possibility that disease transmission pathways in The Netherlands outbreak might be related to high densities of domestic swine. In this section, a descriptive comparison is presented showing the distribution of domestic swine in the EU relative to the progression of the 1997-98 CSF epidemic.

The first CSF outbreaks in The Netherlands and Spain during the 1997-98 epidemic occurred in areas with relatively high concentrations of domestic swine (Figures 21 and 22). In comparison, the first outbreaks in Belgium and Italy occurred in areas with relatively low concentrations of domestic swine (Figures 23 and 24). The extent of the spread following these first outbreaks was considerably greater in the Netherlands and Spain (which had 429 and 99 outbreaks respectively) than it was in Belgium (eight outbreaks) and Italy (two outbreaks that could be attributed with certainty to the epidemic) [11-55, 57].

In The Netherlands (Figure 21), nearly all of the CSF outbreaks during the 1997-98 epidemic occurred in the southern part of the country in one of the most dense swine production areas in the world [36, 37]. The locations of outbreaks that occurred prior to the detection of the epidemic (outbreaks that occurred through March 11, 1997) and the establishment of movement restriction areas that reflect quarantine and surveillance zones are also shown in the figure [44, 57, 58]. The density in this region played a substantial role in the severe and rapid spread that followed the initial outbreak [7].

In Spain (Figure 22), domestic swine are somewhat concentrated in a large area in the northern part of the country and another large area in the southern part of the country. The central part of the country between these two areas has fewer pigs [37]. The first outbreak in Spain occurred in the Province of Lerida in the northeast of Spain in an area of intense swine production. In addition, most of the CSF outbreaks that occurred in Spain during the 1997-98 epidemic also occurred in the Province of Lerida. Several other provinces throughout the country were also involved but with fewer infected herds [8, 13, 39-43, 45-46, 48-55, 59, 60].

In Belgium (Figure 23), much of the domestic swine population is concentrated in the northwest part of the country, particularly in the area of West Vlaanderen [36, 38]. Between 1997 and 2000, only eight CSF outbreaks occurred in Belgium. All of these occurred in 1997 and were the result of secondary spread from The Netherlands during the 1997-98 epidemic.

The first outbreak of the epidemic in Belgium was confirmed on June 30, 1997. and was attributed to human and transport contact with The Netherlands. This first outbreak occurred in the northeast part of the country in the area of Limburg and the remaining seven also occurred in this area. The area of Limburg has a relatively small portion of the domesticated swine population in Belgium [36, 38]. The seven subsequent Belgian outbreaks were attributed to either the purchase of piglets from the first infected Belgian premises or simply proximity spread from this premises [56].

Belgian authorities took quick action against disease spread. In addition to the eight farms where CSF was confirmed, Belgian authorities depopulated an additional 56 farms with known or suspected contact. This was accomplished within a few weeks.

In mainland Italy (Figure 24) most of the domestic swine are concentrated in the Po Valley area in the Region of Lombardia in the north-central part of the country [36, 38]. CSF outbreaks, however, occurred in various locations throughout the country during the 1997-1999 period.

Italy reported no outbreaks in 2000. The two outbreaks that could be attributed with certainty to secondary spread from The Netherlands occurred in 1998 in the Regions of Umbria and Campania, considerably south of the main concentration of domesticated swine [12, 27, 28].

The descriptive comparisons presented in this section support the hypothesis that secondary spread of CSF is more extensive in areas with high densities of domestic swine (The Netherlands and Spain). Less spread may have occurred in areas of low density (Belgium and Italy). However, quick action by Belgian authorities to halt the spread of CSF may have contributed significantly, also.

Temporal Trends in Primary Versus Secondary Outbreaks

For purposes of this discussion, APHIS is defining a primary outbreak as one that occurred in domestic swine in a previously free area. The smallest area under consideration by APHIS in this definition is a county-level equivalent (e.g., kreis) that had not recently reported a CSF outbreak attributed to wild boar, swill feeding, or any other (including unknown) cause. Secondary outbreaks are defined as other outbreaks and are generally attributed to causes such as the purchase of animals or contacts with persons or transport equipment from other premises with infected domesticated swine.

As previously mentioned, since 1997 only Germany and Italy experienced CSF outbreaks in domesticated swine that have been attributed directly to contact with wild boar [8, 11-13, 15-18, 24, 27, 39-43, 45-57, 61-64]. Secondary spread from most of these outbreaks since 1997 has been limited [15, 24, 25], and the degree of secondary spread has decreased with time. In 1999, no secondary spread occurred from six outbreaks in Germany.

The most extreme example of secondary spread occurred in the 1997-98 epidemic. This epidemic accounts for most of the outbreaks that have occurred in the EU since 1997. All of the outbreaks that occurred since 1997 in The Netherlands, Belgium, and Spain, and at least two of the outbreaks in Italy, have been the result of secondary spread from this outbreak. At least 538 of the 621 CSF outbreaks (87 percent) that occurred in the EU in 1997 through 2000 to date (excluding Sardinia and the United Kingdom) can be attributed to secondary spread from this single outbreak. The geographic scope of this secondary spread was quite extensive.

Furthermore, based on information presented in this report, these secondary outbreaks generally occurred in geographic locations distant from uninfected or infected wild boar populations. Therefore, the vast majority of CSF outbreaks occurring in the EU since 1997 were not geographically associated with wild boar populations.
Excluding the 1997-1998 epidemic and outbreaks in Sardinia and the United Kingdom, there were 82 remaining CSF outbreaks in the EU in 1997 through July 2000. Of these, 18 occurred in mainland Italy and 64 occurred in Germany (Figure 25) [11, 15, 24, 27-28, 32, 57].

By the definition presented above, there were 22 primary outbreaks in Germany since 1997. All of the outbreaks in Germany in 1999 and 2000 to date (eight in total) are considered primary outbreaks. No outbreak in Germany in 1999 or 2000 had any secondary spread [2, 15, 24-25]. These outbreaks occurred primarily in areas that were already under EU restriction because disease had been detected in wild boar. APHIS attributes lack of disease spread to movement restrictions as well as increased surveillance and control mechanisms required by EU legislation [23].

In 1997 and 1998, (again excluding the epidemic that began in Paderborn and moved through The Netherlands, Belgium, Spain, and Italy), there were 14 primary outbreaks and 42 secondary outbreaks in Germany for an average of 3 secondary outbreaks per primary outbreak. Since 1997, the sources of 18 outbreaks in Germany were attributed to unknown causes [15, 24-25].

Areas of Germany, mainland Italy, and France where CSF infection has been detected in wild boar since 1997 are shown in Figure 26 [2, 16-18, 20, 22, 24, 65].

Since 1997, therefore, 538 secondary outbreaks that occurred in one multi-country epidemic were geographically distant from the primary outbreak. An average of three (declining to zero in 1999 and 2000) secondary outbreaks occurred per primary outbreak in Germany in close proximity to the primary outbreak and any infected wild boar.

Italy has reported two primary outbreaks on the mainland since 1997 [18, 27]. One of these resulted in no secondary spread, and the other resulted in two secondary outbreaks. Twelve outbreaks that occurred in mainland Italy in 1997 were in close proximity to a primary outbreak in 1996 that resulted from infection in wild boar.

Close proximity of wild boar populations to material eligible for export might increase the probability of disease transmission from boar to breeding animals and the CSF risk to the US. However, EU restrictions because of disease in wild boar should reduce this risk effectively. Taken together, the observations presented in this report suggest that the risk of importing CSF-infected material from areas of the EU that are in close proximity to infected wild boar is not greater than the risk of importing infected material from areas that are geographically distant from primary outbreaks caused by wild boar.

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Table 1

Total Wild Boar Population for all other EU Member States

COUNTRY	TOTAL WILD BOAR POPULATION
Austria	No Data
Denmark	No Data
Finland	300
Greece	500
Irish Republic	0
Luxembourg	15,000
Portugal	60,000
Sweden	10,000
United Kingdom	100

Figure 1
EU Member States Affected by CSF During 1997-2000

Figure 2
1993-96 Domesticated Swine Exports from Netherlands to EU Member States

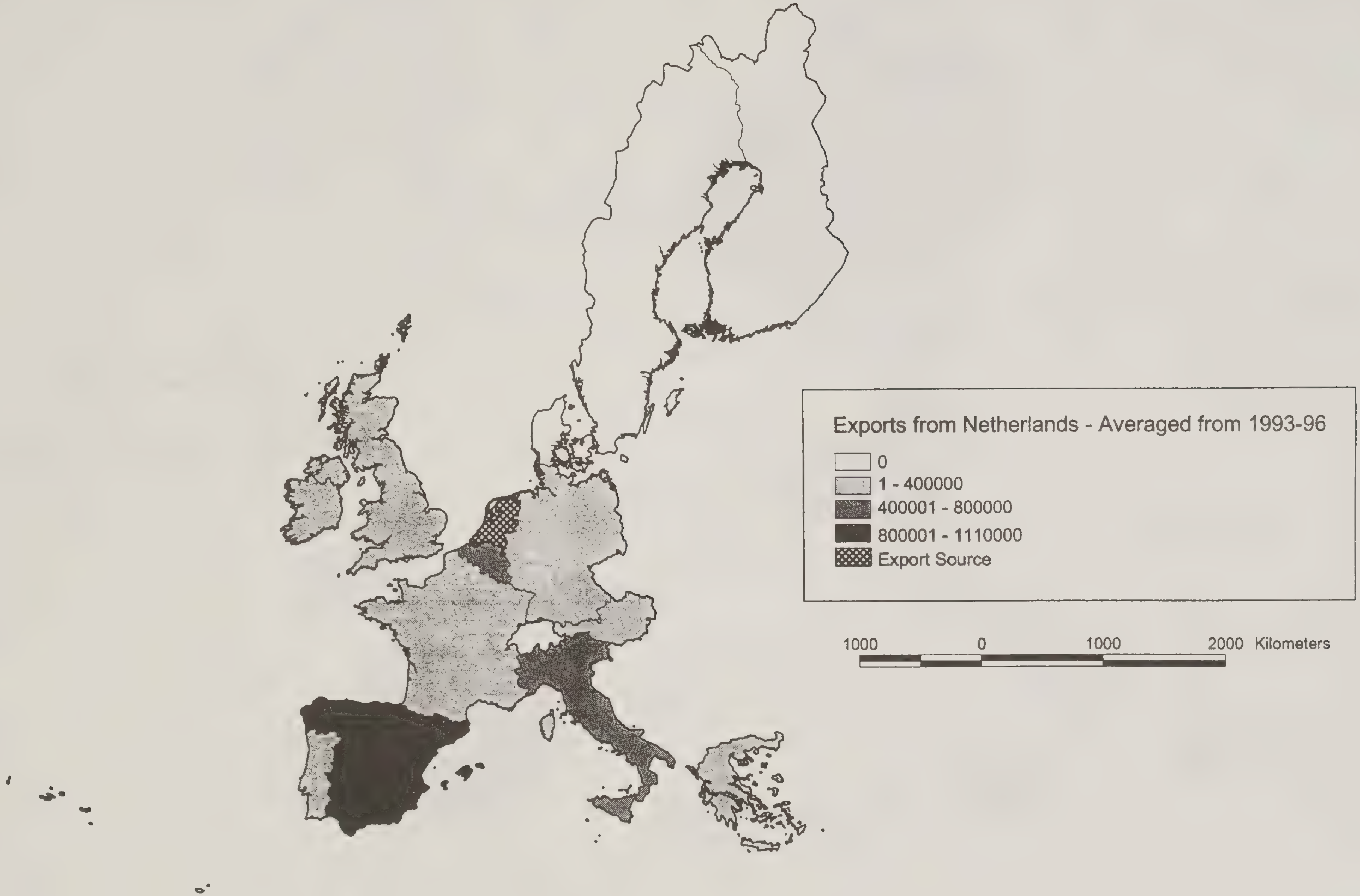

Figure 3
1997-98 CSF Epidemic in Domesticated Swine

Figure 9

Germany - Wild Boar Population and Wild Boar Kills

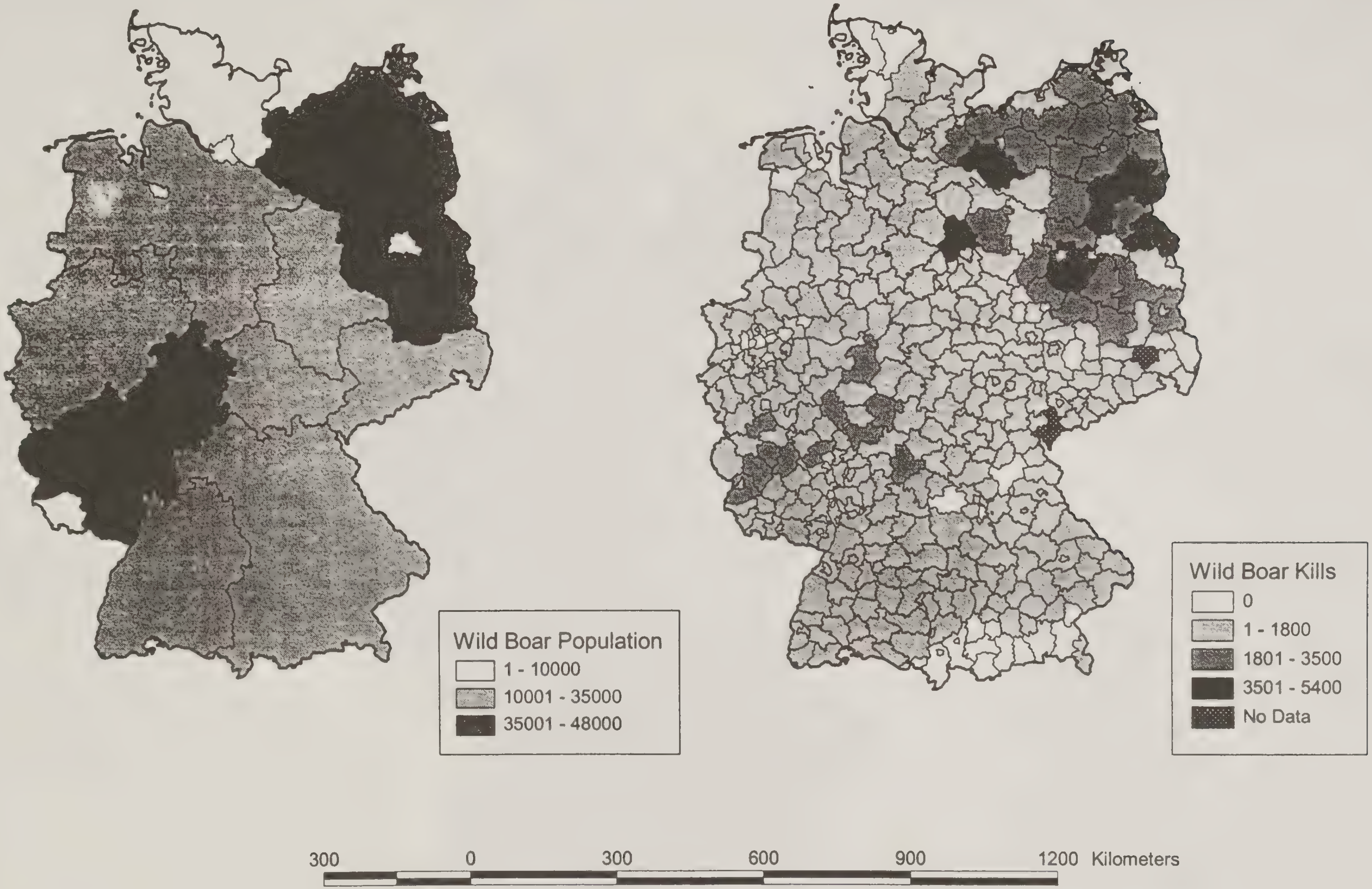

Figure 10
Germany - Wild Boar Population Relative to Breeding Swine Exports (1999)

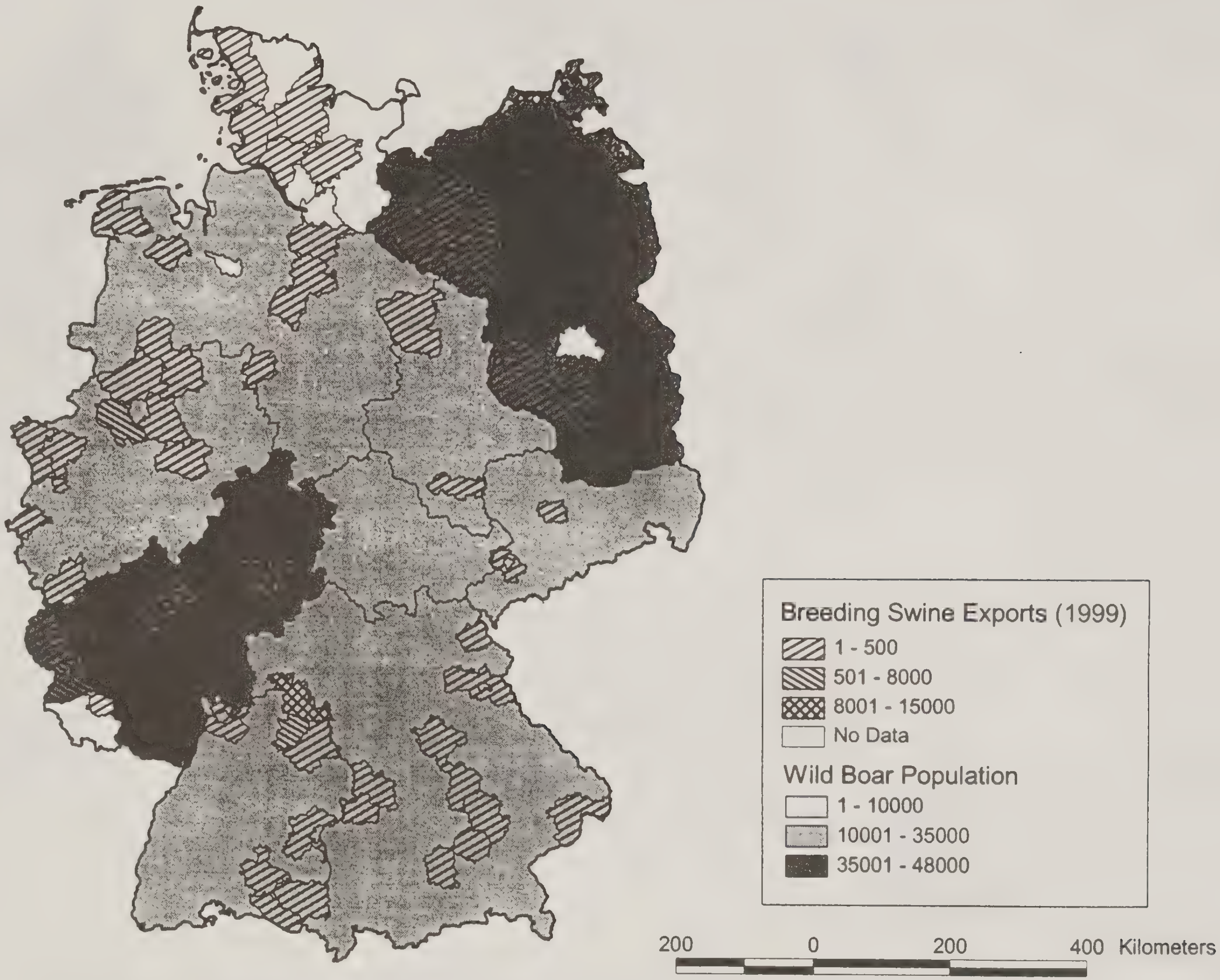

Figure 11
Germany - Wild Boar Kills and Breeding Swine Exports (1999)

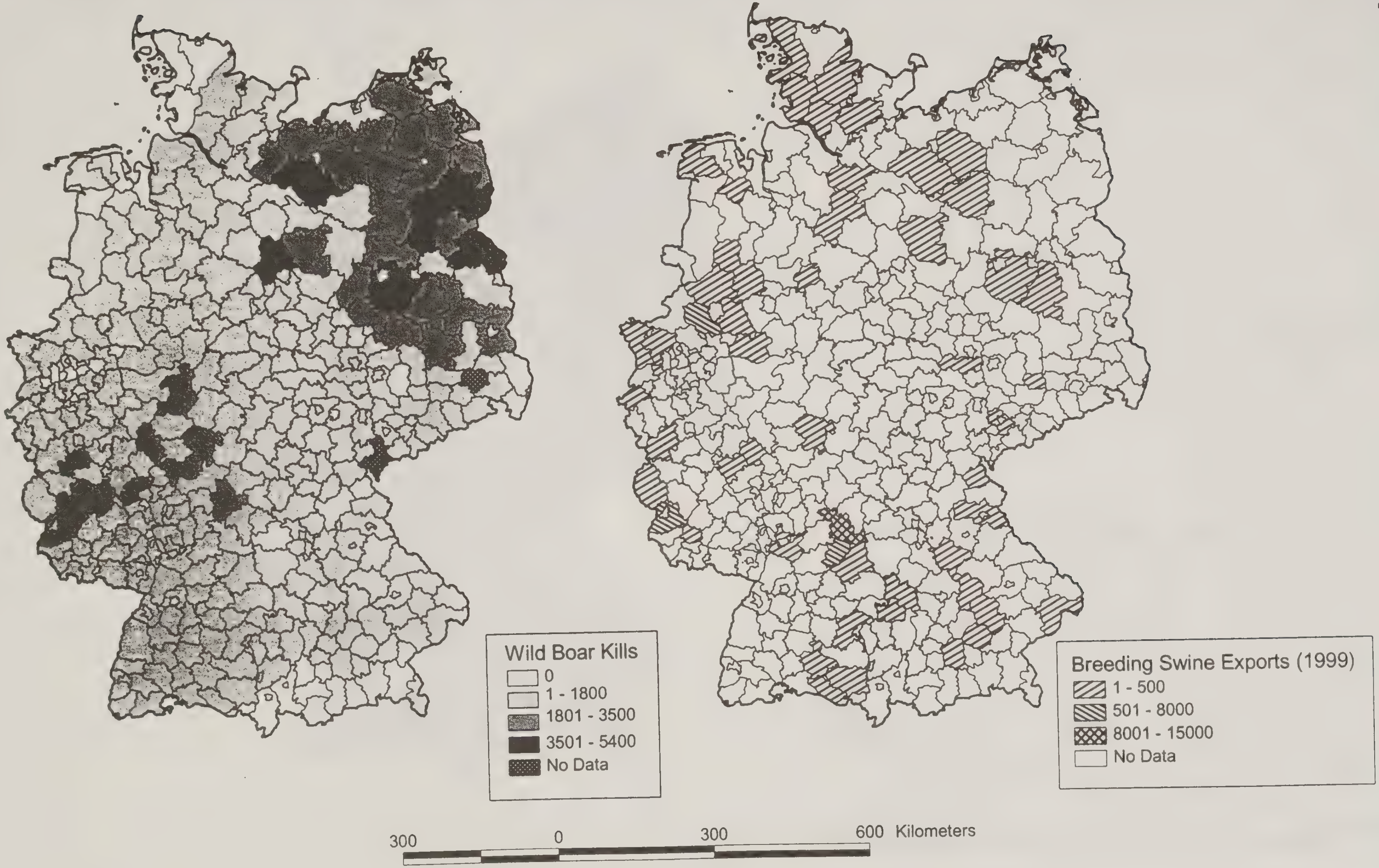

Figure 12

Germany - Wild Boar Population Relative to Swine Semen Exports (1999) and Swine Semen Centers

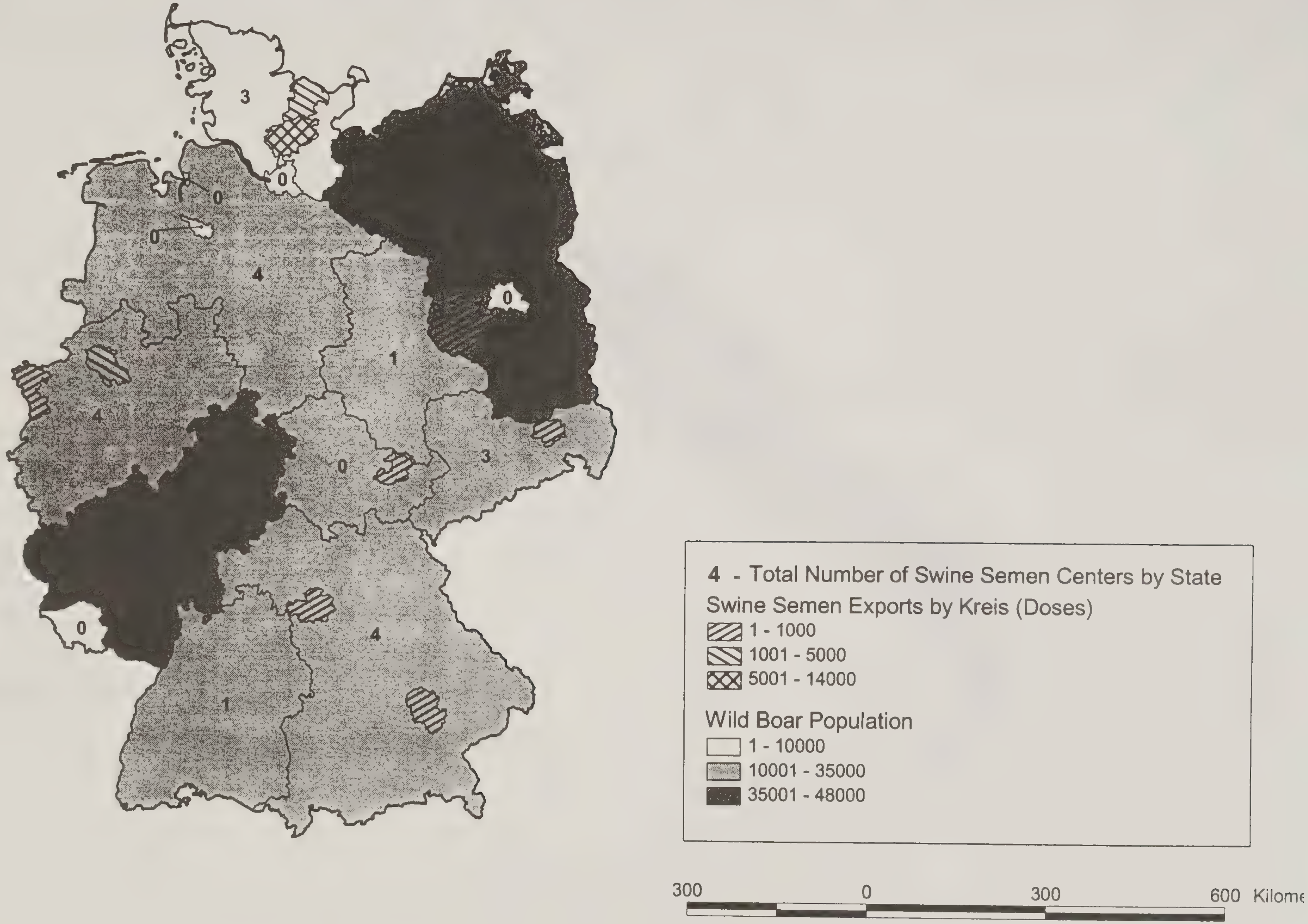

Figure 13

Italy - Wild Boar Presence Relative to Swine Semen Centers

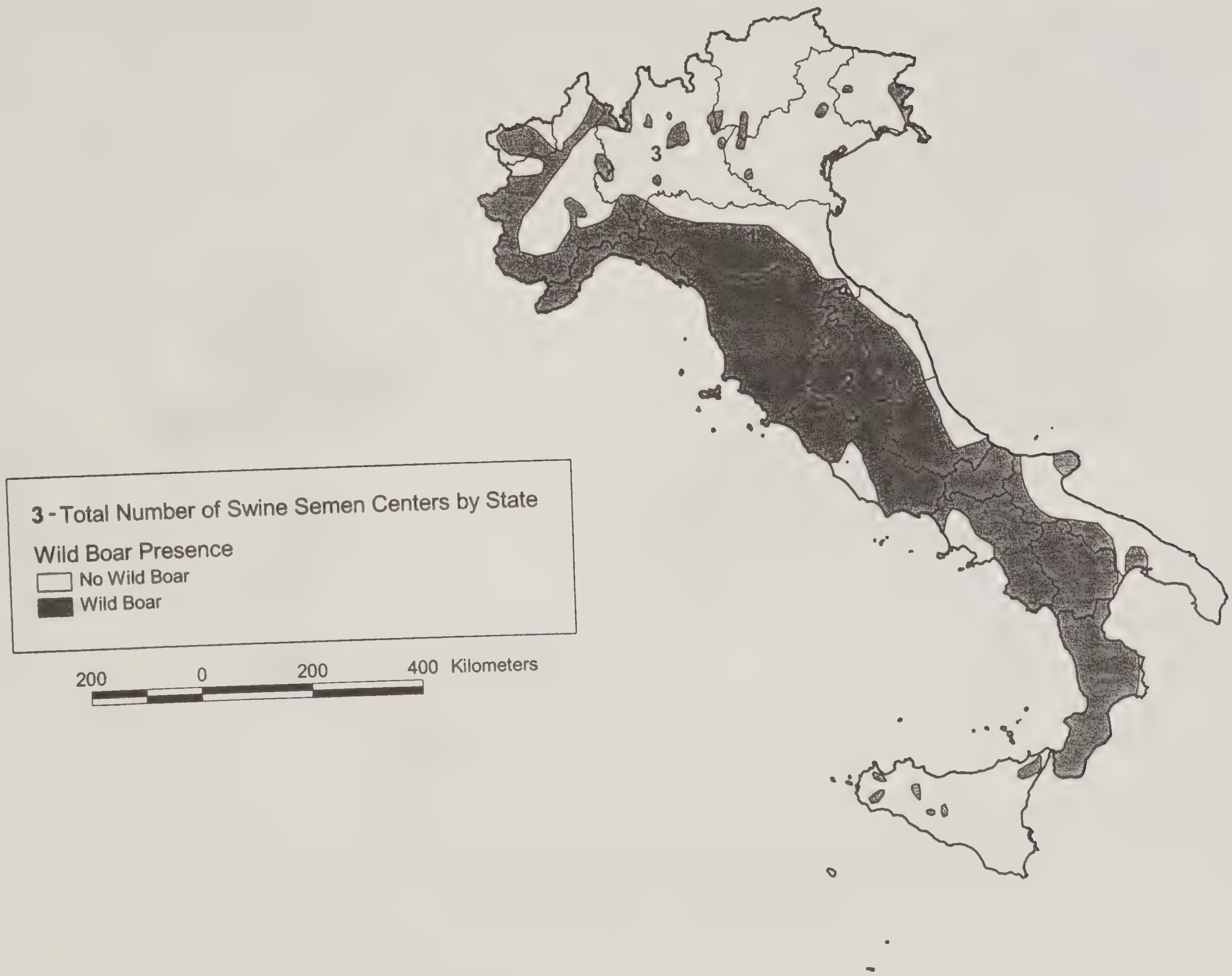

Figure 14

Netherlands - Wild Boar Population Relative to Breeding Swine Exports (1999)

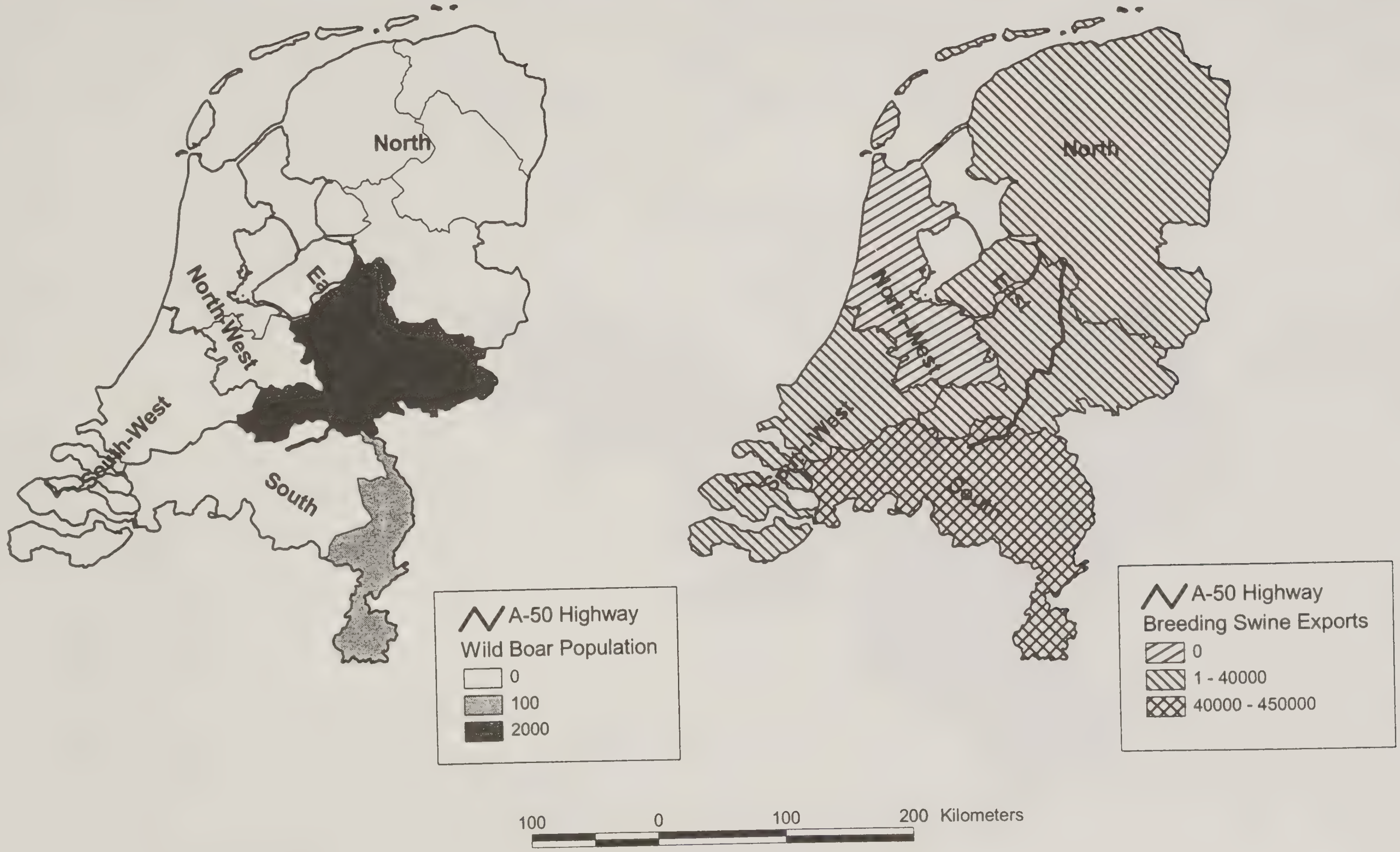

Figure 15

Belgium - Wild Boar Population Relative to Breeding Swine Exports (1999)

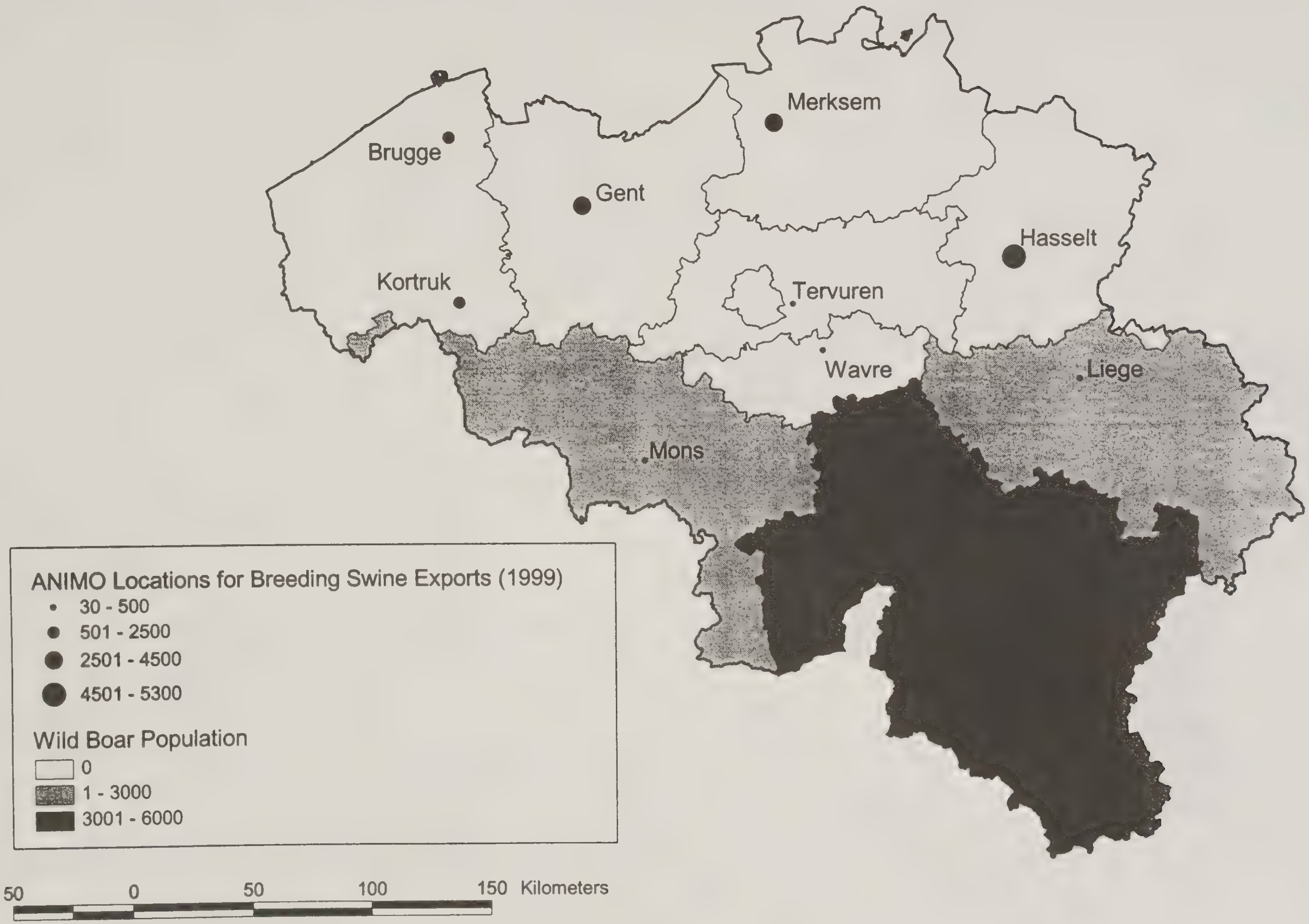

Figure 16

Belgium - Wild Boar Population Relative to Swine Semen Exports (1999) and Swine Semen Centers

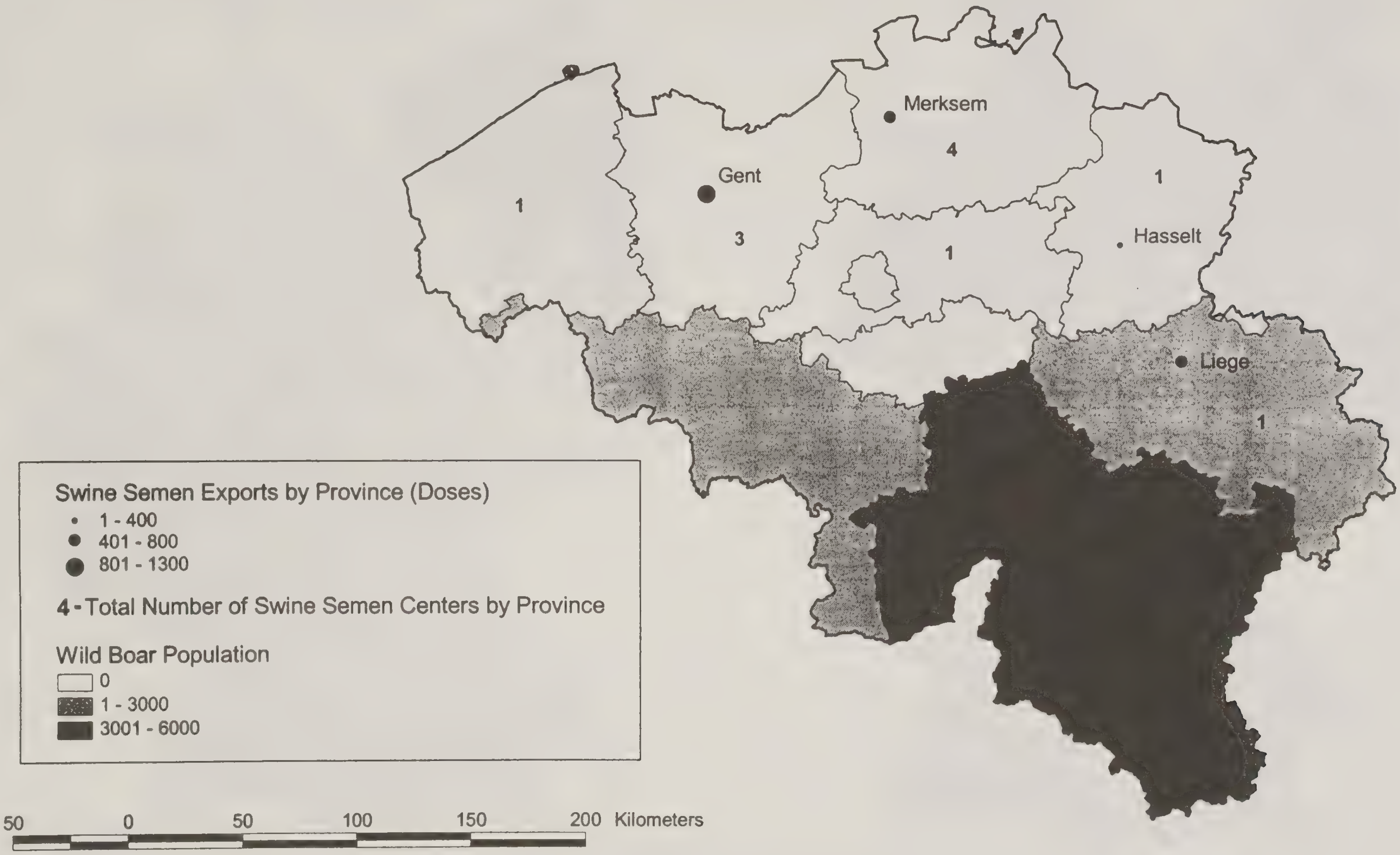

Figure 17

Germany - Wild Boar Population Relative to Domesticated Swine Population

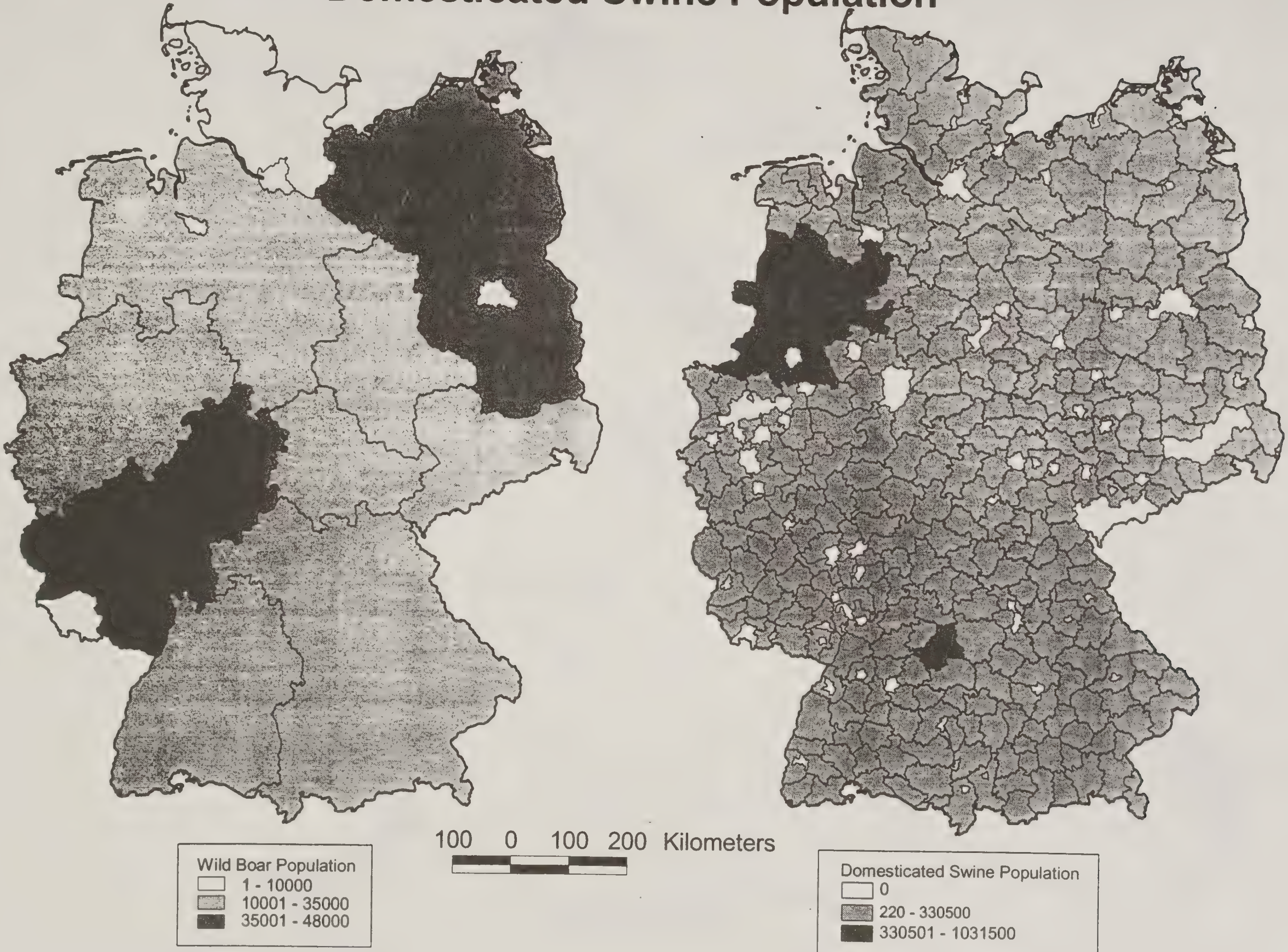

Figure 18

Italy - Comparison of Hypsography, Swine Demographics, and Wild Boar Presence

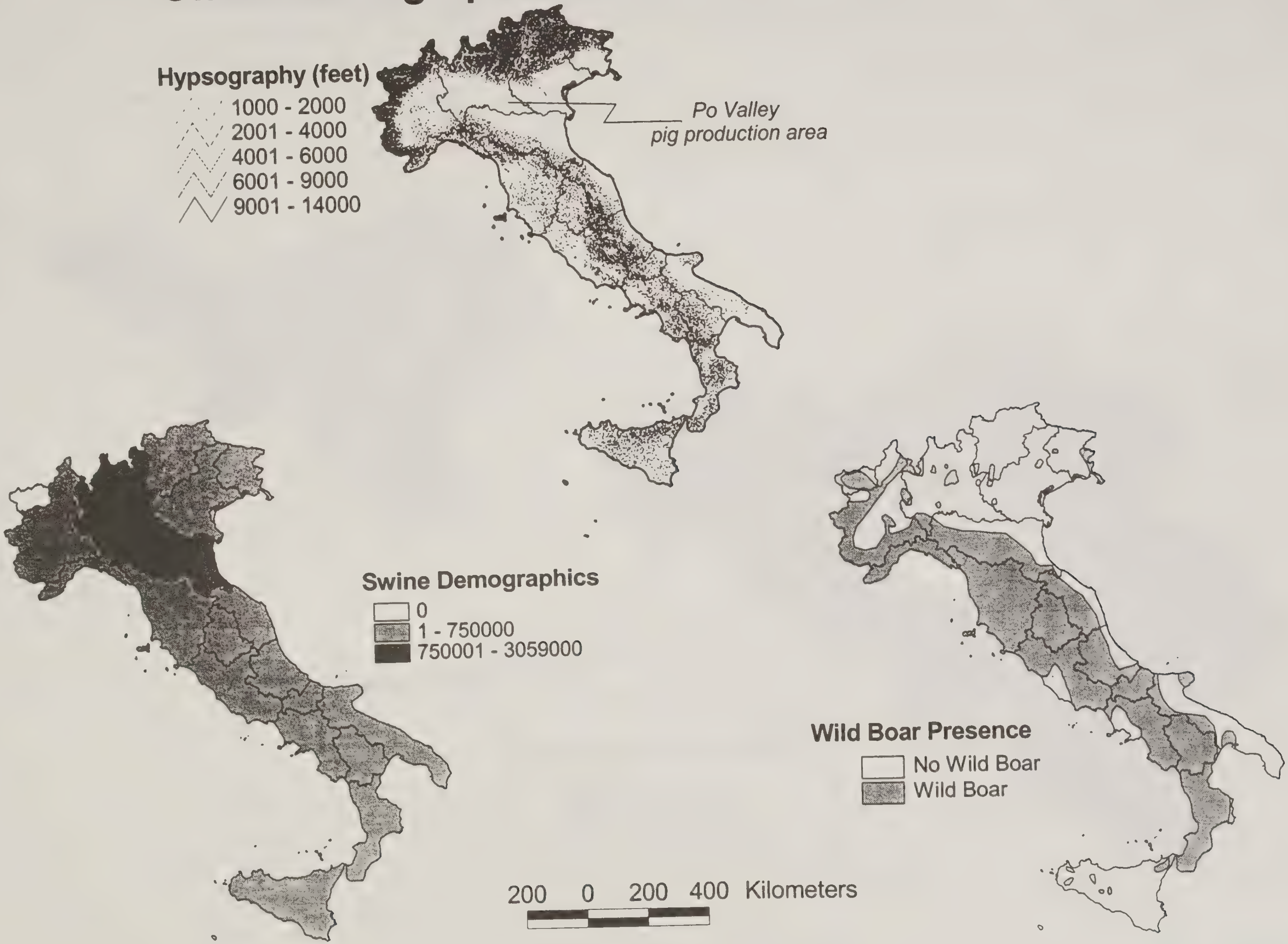

Figure 19

Belgium - Wild Boar Population Relative to Domesticated Swine Population

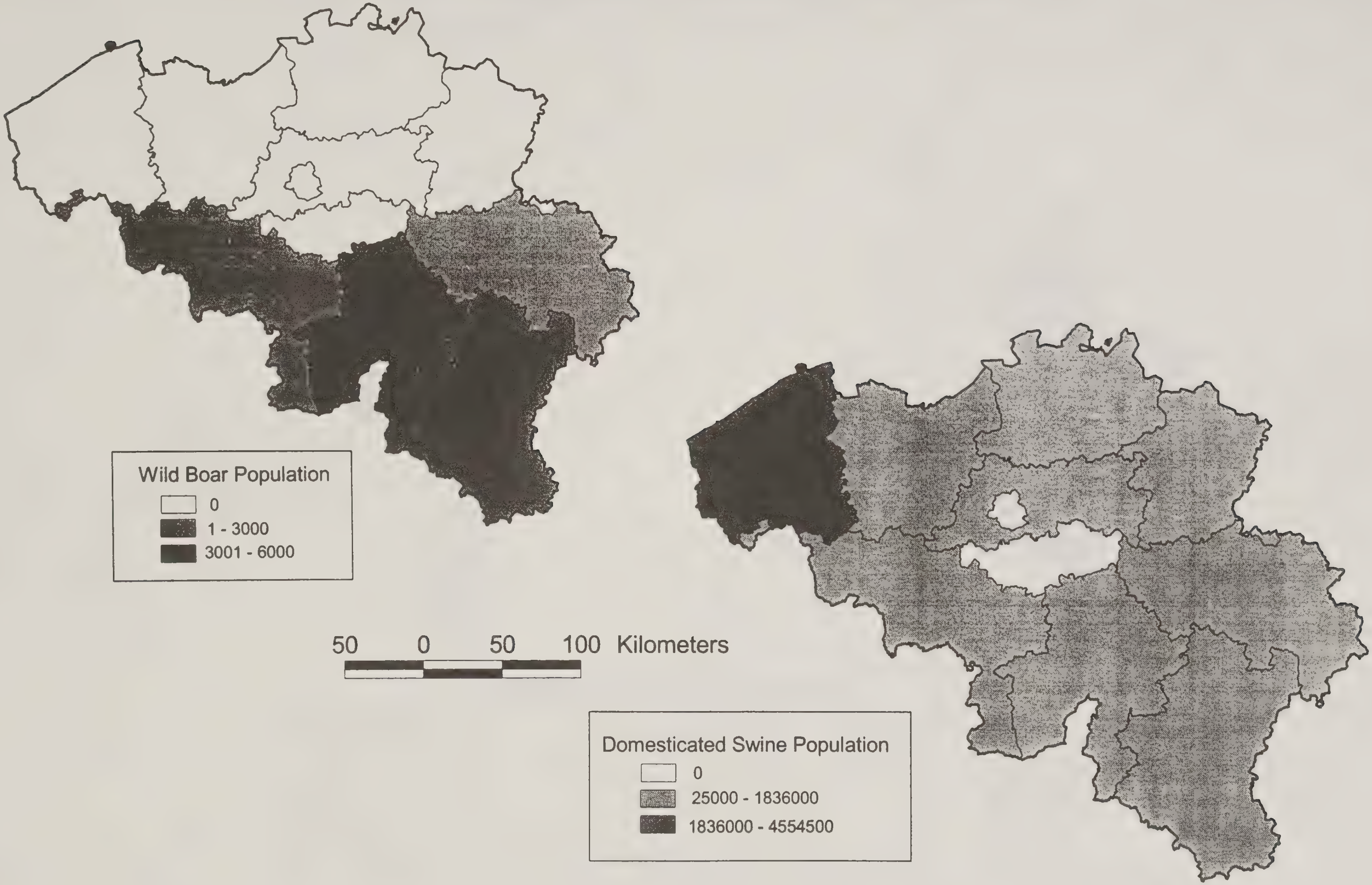

Figure 20
Netherlands - Wild Boar Population Relative to Domesticated Swine Population

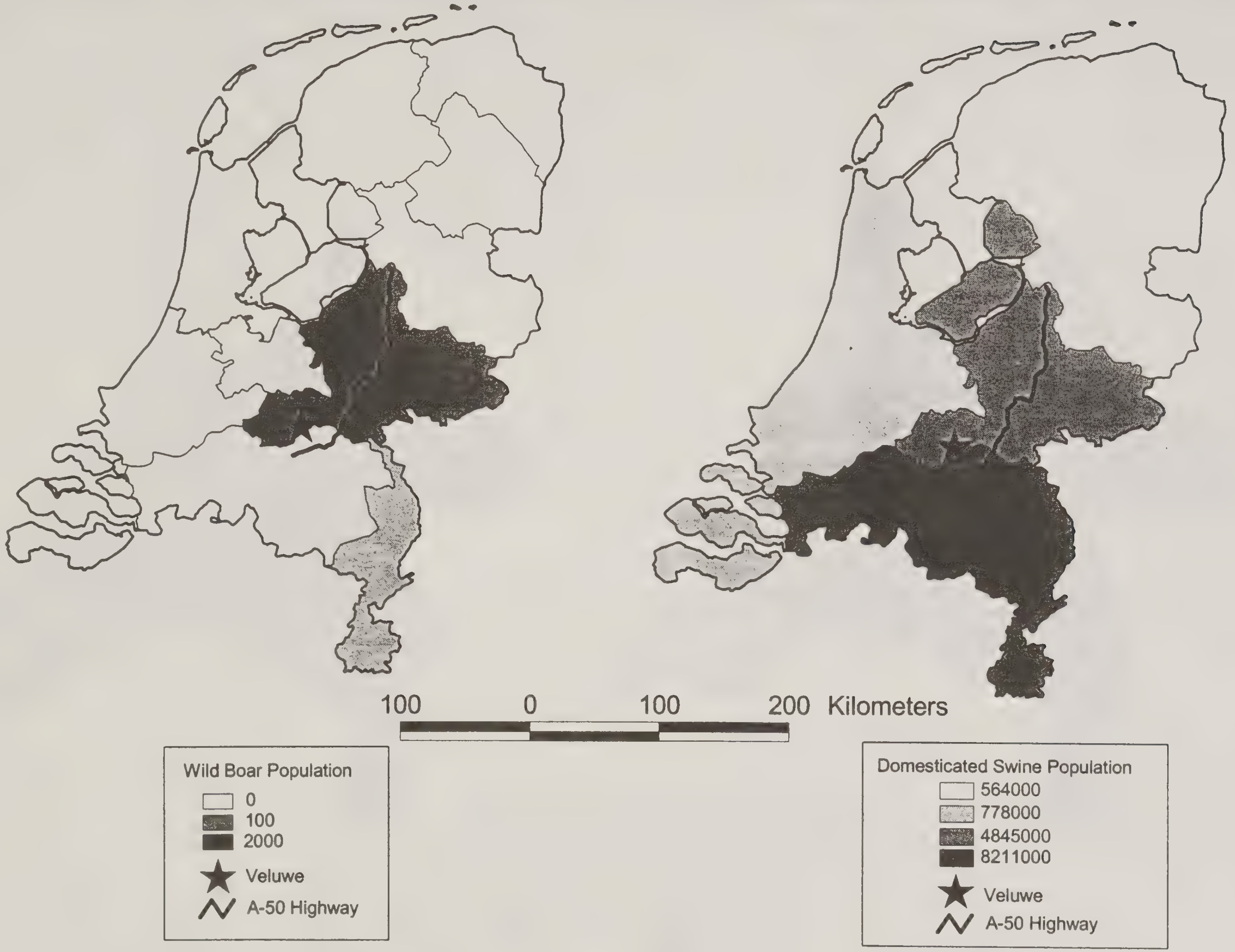

Figure 21

Netherlands - 1997 CSF Outbreaks through March 11, 1997 in Domesticated Swine Relative to 1995 Swine Demographics

Netherlands - Summary of 1997 and 1998 CSF Outbreaks in Domesticated Swine Relative to 1995 Swine Demographics

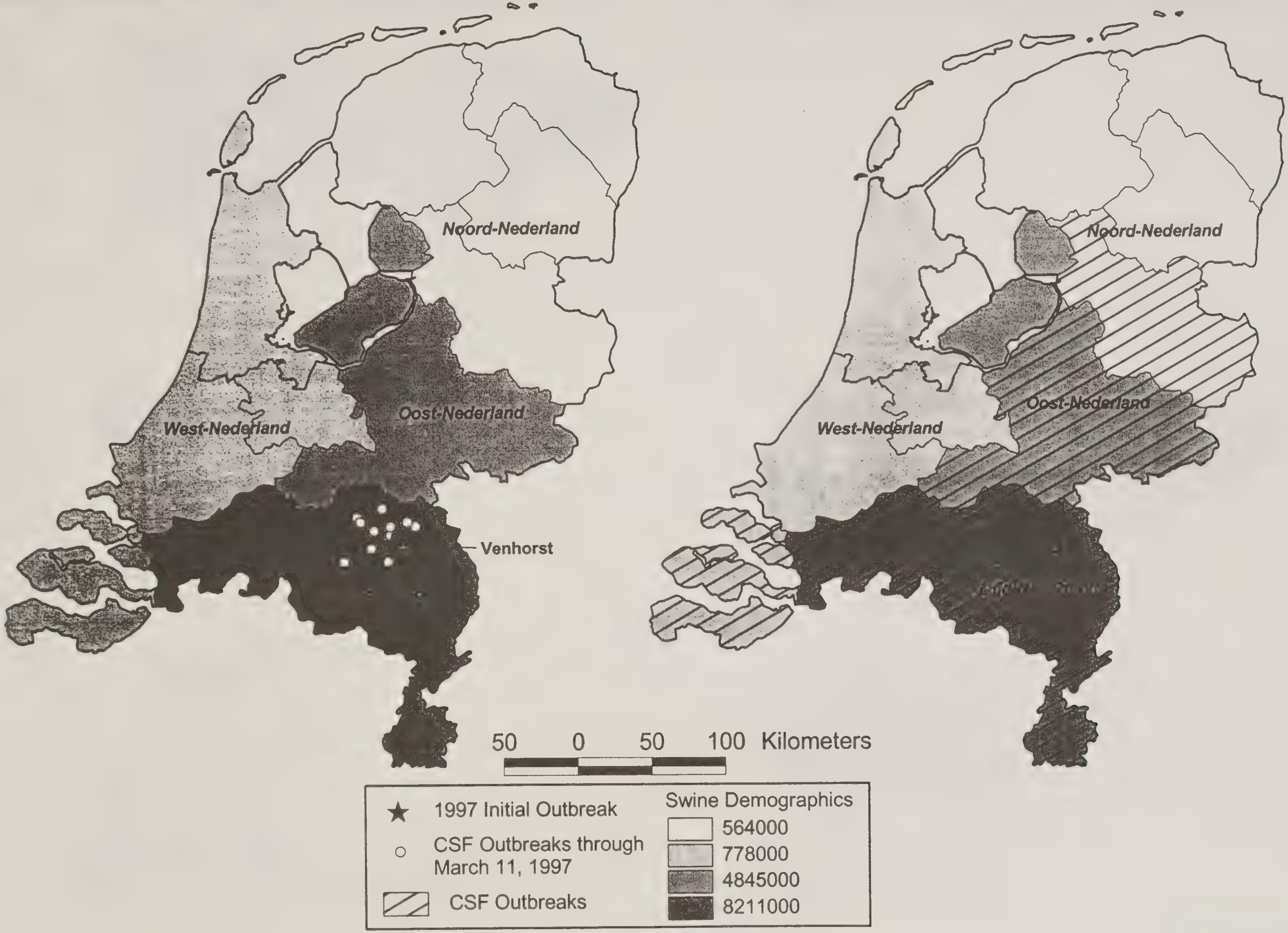

Figure 22

Spain - 1997 and 1998 CSF Outbreaks in Domesticated Swine Relative to 1993 Swine Demographics

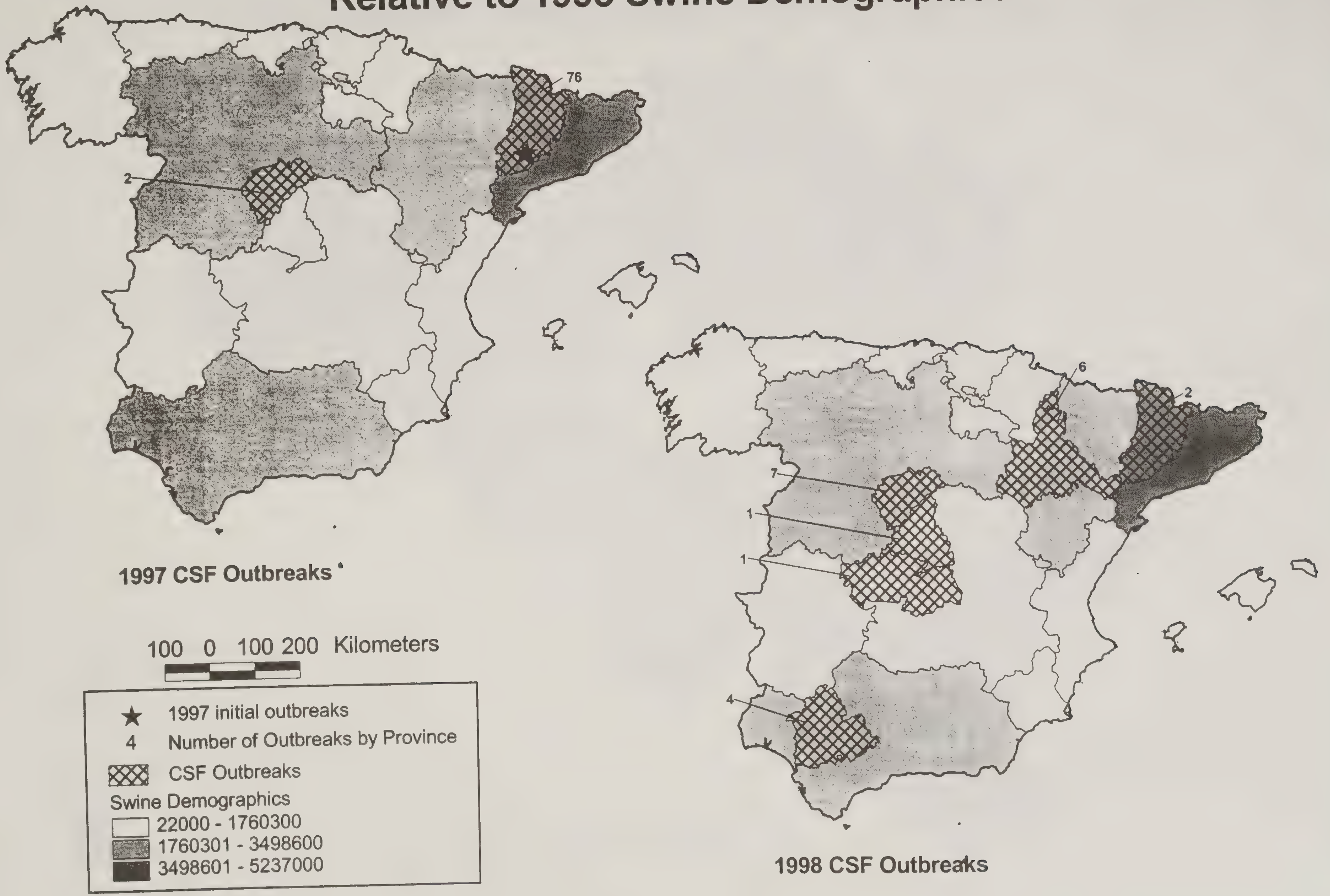

Figure 23

Belgium - 1997 CSF Outbreaks in Domesticated Swine Relative to 1996 Swine Demographics

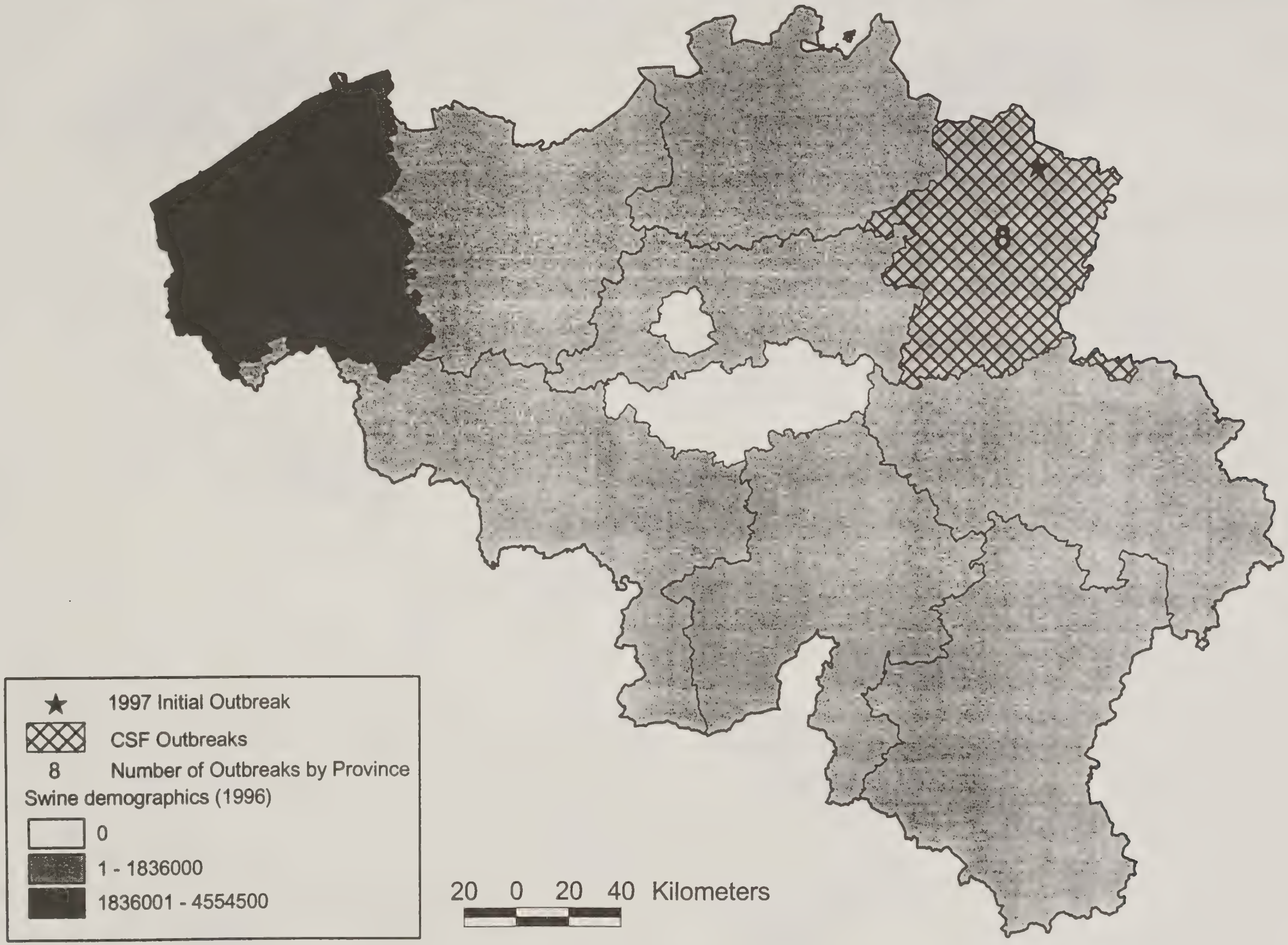

Figure 24

Italy - 1997, 1998, and 1999 CSF Outbreaks in Domesticated Swine Relative to 1994 Swine Demographics

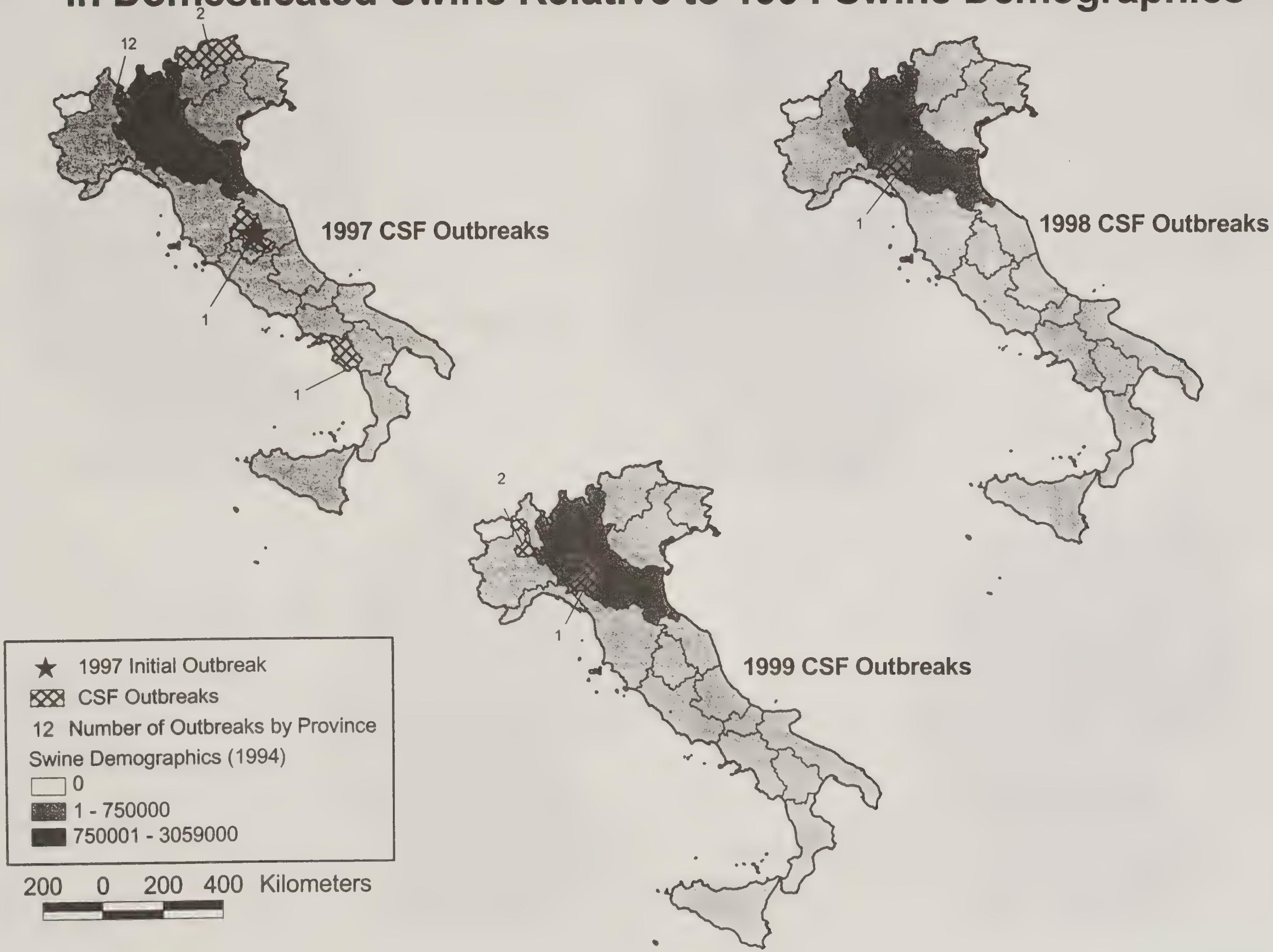

Figure 25

Germany - 1997, 1998, 1999, and 2000 CSF Outbreaks in Domesticated Swine Relative to 1996 Swine Demographics

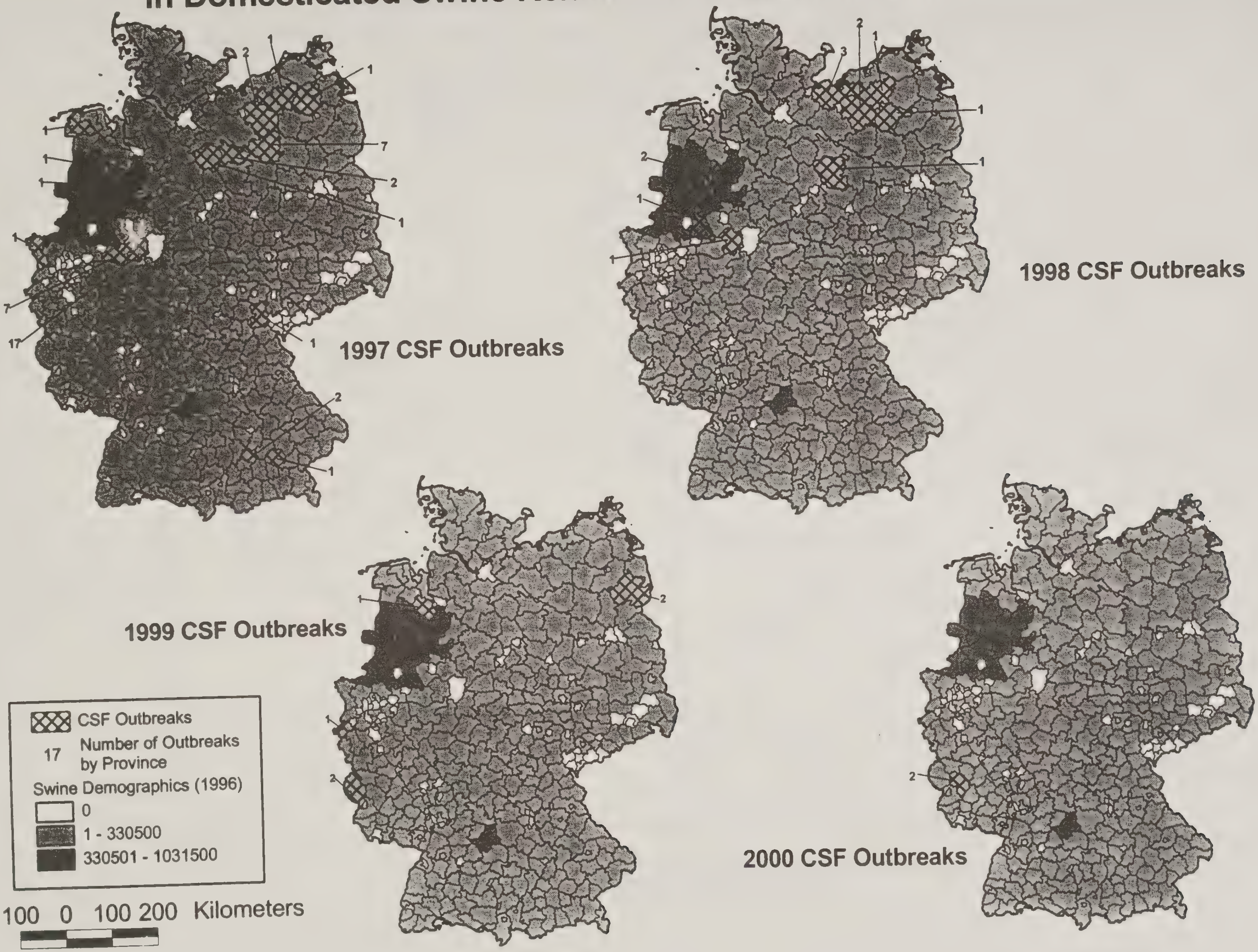

Figure 26

CSF Detected in Wild Boar (1997-2000)